

## ANGIOGRAPHY & HYBRID THEATRE EQUIPMENT AND RELATED SERVICES

### LOT 2 – RELATED SERVICES

Lot 2 covers the provision of services relating to Lot 1 Angiography Imaging, Hybrid Operating Theatres, Cardiac Catheterisation Monitoring & Related Equipment, for the avoidance of doubt, all standards pertaining to the equipment provided in Lot 1 also apply to any equipment provided as part of the service provision in Lot 2.

#### **SUBCATEGORY 1 – MANAGED SERVICES**

In all cases this specification relates to the Managed Service Provision for, but not limited to, the below:

- The purchase and provision of equipment,
- Installation and commissioning of equipment involving any associated enabling works, building works or turnkey provision,
- Software & IT Integration as applicable on a case by case basis for each Managed Service
- Inventory Management Systems, including Inventory Management systems operated by the Participating Authority's personnel and the Service Provider's own staff,
- User training,
- Disposal & replacement of assets,
- Analysis and modelling,
- Detailed reporting to enable maximum value from the service, and
- Any project planning and financing opportunities.

#### **Criteria 1: Service Offering**

1. The Service Provider **must** be able to provide and maintain equipment and machines required for Interventional Rooms, Hybrid Theatres and Catheter Laboratories services. (PASS/FAIL)
2. The Service Provider **must** accept all responsibility for delivery of the Managed Service as detailed in each Participating Authority specification and contract. (PASS/FAIL)
3. The Service Provider and any third-party sub-contractor engaged by the Managed Service Provider **must** provide safe, efficient, responsive, comprehensive, and effective services which meet all required guidelines, accreditation, and statutory regulations. (PASS/FAIL)
4. The Service Provider **must** comply with Medical Devices Agency safety, hazard and device alert notices. (PASS/FAIL)
5. The Service Provider **must** be able to operate in departments staffed with NHS-employed clinical & non-clinical personnel (PASS/FAIL)
6. The Service provider **must** monitor the performance of the contract and obligations under this Framework on behalf of the Participating Authorities, providing regular feedback in agreed formats to

the Participating Authority including but not limited to KPIs Performance, Delivery Issues, Preventative Maintenance, Training Plans, Strategy / Planning Updates and Major Incident Responses as detailed in the specifications of the Participating Authorities. (PASS/FAIL)

7. The Service provider **must** administer the contract to ensure that all Contract Changes are tracked and approved by each Participating Authority to whom the changes relate. (CCN/Notices etc) (PASS/FAIL)
8. An Implementation Plan will be jointly agreed with each Participating Authority, to include transition from the existing service provision and where applicable. Applicable to what? The Service Provider **must** ensure that service continuity is maintained throughout the transition process, in accordance with the detail agreed in the Implementation Plan. This **must** include but is not limited to; detailed plans with proposed time intervals for each stage involved; responsibilities (RACI), and; risk mitigation. This will be agreed on a case by case basis to meet Participating Authorities' requirements (PASS/FAIL)
9. The Service Provider must agree a schedule of contacts for each contract and detail the escalation contacts and routes in a Service Level Agreement. These contacts will vary on a project by project basis, but must include individuals who can escalate service, commercial and technical issues.
10. The Service Provider **must** provide Participating Authorities with an Exit Plan within six months of the Managed Service going live. The Exit plan will be agreed on a case by case basis with each Participating Authority and will include, but is not limited to the Participating Authority's approach to managing the Exit and decommissioning/ removal of equipment, the commitment to Service continuity and how they will support the incoming Service Provider through the transition in a professional and competent manner whilst minimising any potential risk to Patient Safety. (PASS/FAIL)
11. The Service Provider **must** permit any Trust, health authority, primary care organisation or other staff nominated by the Participating Authority to inspect the managed premises and records with or without prior notification. (PASS/FAIL)
12. Any complaints from patients or relatives regarding the service **must** be forwarded immediately to the Participating Authority (PASS/FAIL)
13. The Service Provider **must** comply with the Participating Authority's procedure for reporting and investigating serious untoward incidents. (PASS/FAIL)
14. The Service Provider **must** be able to provide a detailed business continuity plan for each call-off agreement entered into under the Framework. (PASS/FAIL)
15. Upon expiry of the contract, the outgoing Service Provider **must** support any incoming Service Provider during the transition period in order to provide continuity of service for the Participating Authority. (PASS/FAIL)
16. The Service Provider will be expected to invoice the Participating Authority within the timescale and format as agreed and specific to each contract. (PASS/FAIL)
17. The cost of delivery and installation of all equipment and products associated with the service is the sole responsibility of the Service Provider. (PASS/FAIL)

## Criteria 2: Training

18. The Service provider **must** ensure that all training through the life of the agreement is delivered to ensure that all users are competent with the equipment;
19. Contract Implementation Training: The Participating Authority **must** sign off to confirm that an acceptable level of user training has taken place. (PASS/FAIL)
20. Ongoing/refresher Training: **must** be monitored throughout the life of the agreement during the management review meetings. Participating Authorities will inform the Service Provider where any ongoing/refresher training is required. (PASS FAIL)
21. All training **must** be provided as an integral part of the Managed Service and should not attract an additional fee, unless otherwise agreed with Participating Authorities on a case by case basis. (PASS FAIL)

## Criteria 3: IT, Software & Integration

22. Where IT / IT integration is required the Service Provider or any delegated sub-contractor **must** provide all necessary hardware and software required to deliver the Service and provide these in a manner consistent with each Participating Authorities IT policies. States the obvious (PASS FAIL)
23. Software and hardware supplied **must** meet any requirements set out by the Participating Authority, this includes requirements set by NHSE/I, NHSD or NHSx in terms of standards and specification to ensure integration with health systems. (PASS FAIL)
24. The Service provider **must** be able to provide a secure and robust archive storage & retrieval solution based on the Participating Authority's record retention policy (This may extend up to 30 years). (PASS FAIL)
25. The Service provider **must** provide, and in accordance with each Participating Authority's IT policies, any and all associated support and maintenance required to ensure the optimal performance of the system whilst minimising / mitigating potential risk of downtime. (PASS/FAIL)

## Criteria 4: Supporting Innovation & Added Value

26. Service Providers **must** provide Participating Authorities with the option to engage in Innovation and Added Value opportunities. Support and direction must be available to Participating Authorities to review, assess and implement any innovative and added value opportunities. This can include, but is not limited to, new technology, supporting trials, sharing clinical good practice, financial innovation, such as risk reward initiatives and cost per patient/procedure models and developing joint

initiatives. Where joint initiatives are developed consideration by be given to potential Participating Authority Intellectual Property Rights. (PASS/FAIL)

27. Where innovation is offered, MDR Regulation (as amended by NHSX) **must** be adhered to where relevant. (PASS/FAIL)
28. There may be a requirement to manage and novate existing contracts into the Managed Equipment Service agreement as and when required throughout the lifetime of the agreement. This will be agreed with the Participating Authority on a case by case basis with the Service Provider.
29. Where required, the Service Provider may be requested to provide additional support which may include, but not limited to; Enabling Works, Solution Integration, Information Management.
30. Full technical specifications of the product lines awarded to the Framework Agreement **must** be made available to NHS Supply Chain on request during the term of the Framework Agreement. Service Providers must notify NHS Supply Chain immediately about any proposed changes to the Technical Specifications throughout the term of the Framework Agreement. (PASS / FAIL)
31. If changes to the Technical Specification of any product line awarded to the Framework Agreement mean that the product line no longer meets the minimum requirements outlined in the Specification, NHS Supply Chain reserves the right to exclude that product line from the Framework Agreement. (PASS / FAIL)

## **SUBCATEGORY 2 – MOBILE CARDIAC CATHETERISATION LABORATORIES**

Lot 2 (Related Services) of this framework also requires provision for the supply of Mobile Cardiac catheterisation laboratories, including qualified staff and equipment, reporting services and non-staffed variations. The service will enable the capture of diagnostic images within a mobile unit (this may include, the supply of vehicular, modular, demountable or re-locatable facilities) at a location as chosen by the Participating Authority which may or may not be on the Participating Authority's site. The results of this image capture will be used to make clinical patient diagnosis.

### **Criteria 1: Service Offering**

1. Fixtures and Fittings **must** include (as a minimum):
  - 1.1. Room Temperature Controls;
  - 1.2. Lighting;
  - 1.3. Storage/lockers;
  - 1.4. Area/room designated for patient changing/preparation;
  - 1.5. Fire suppressants;
  - 1.6. Fire/smoke detectors and alarms;
  - 1.7. Patient alarm/call system;
  - 1.8. IT infrastructure including hardware and software; and
  - 1.9. Furniture (e.g. desk, chairs, clocks, bins etc)

(PASS / FAIL)
  
2. Utilities and other facilities **must** include:
  - 2.1. Water/foul drainage where applicable;
  - 2.2. Power supply (suitable for connection to facility and/or standalone generator) where applicable;
  - 2.3. Uninterruptable power supply;
  - 2.4. Suitable cut-off switches (e.g. gas, electricity);
  - 2.5. Gas banks/storage where applicable;
  - 2.6. Where applicable suitable supply of medical/anaesthetic gases;
  - 2.7. Cat 5 or greater cabling for phone and internet;
  - 2.8. Suitably secure doors and windows; and
  - 2.9. Suitable 24-hour response maintenance and emergency cover
  - 2.10. Where the mobile unit is not situated on the Participating Authority's grounds, general and clinical waste must be disposed of in line with the relevant legal procedures by the service provider

(PASS / FAIL)

3. The Service Provider Must be able to provide EBME (Electro Bio-Medical Engineering) method statement on request from NHS Trusts (PASS / FAIL)

#### **Criteria 2: Staffing**

4. Where a mobile staffed solution is required:
    - 4.1. All staff **must** be suitably trained, experienced, and qualified;
    - 4.2. Clinical staff provided within this Lot **must** hold General Medical Council (GMC) registration;
    - 4.3. All clinical staff **must** be CPD (Continuous Professional Development) certified
    - 4.4. All staff **must** have Disclosure and Barring Service (DBS) checks formally known as Criminal Records Bureau (CRB) completed
    - 4.5. Clinical staff **must** be trained in Basic Life Support (BLS) as a minimum
    - 4.6. Service Providers **must** be able to provide at least one contact name and number so that Participating authorities are able to resolve queries Monday-Friday between the hours of 9am-5pm
    - 4.7. A clinical service lead **must** be provided.
    - 4.8. At least one member of staff (including Radiographers and any other clinical support staff) **must** be skilled and fully qualified in the operation of the (imaging) equipment
- (PASS / FAIL)

#### **Criteria 3: Training**

5. The Service Provider may be required to deliver training to the Participating Authority. If training is required, the Service provider must ensure that all training through the life of the agreement is delivered to ensure that all users are competent with the equipment and facilities provided;
  - 5.1. Contract Implementation Training: The Participating Authority must sign off to confirm that an acceptable level of user training has taken place.
  - 5.2. Ongoing/refresher Training: must be monitored throughout the life of the agreement during the management review meetings. Participating Authorities will inform the Service Provider where any ongoing/refresher training is required.
6. Service providers should be able to provide training to clinical engineering staff, if required.

#### **Criteria 4: IT, Software & Integration**

7. As stated in Service Offer above mobile facilities must include:
  - 7.1. IT infrastructure including hardware and software; and

- 7.2. Cat 5 or greater cabling for phone and internet.
8. Software & IT Integration may be required, as applicable on a case by case basis
9. Where IT / Integration is required, the Service Provider or any delegated sub-contractor must provide:
  - 9.1. all necessary hardware and software required to deliver the Service and provide these in a manner consistent with each Participating Authorities IT policies. This will include but is not limited to any back up and Disaster Recovery provision.
  - 9.2. Software and hardware supplied must meet any requirements set out by NHSE/I, NHSD or NHSx in terms of standards and specification to ensure integration with health systems.
  - 9.3. a secure and robust archive storage & retrieval solution based on the Participating Authority's record retention policy (This may extend up to 30 years).
  - 9.4. in accordance with each Participating Authority's IT policies, any and all associated support and maintenance required to ensure the optimal performance of the system whilst minimising / mitigating potential risk of downtime.
10. Where IT services are required, the Service provider may be required to provide additional IT services, including, but not limited to:
  - 10.1. Software and software upgrades
  - 10.2. IT integration
  - 10.3. Inventory Management Systems (operated both by Trust staff and Service Provider's staff)
  - 10.4. IT Services which Capture, record and upload current and future data items
  - 10.5. IT Services which Link to Electronic Patient Records
  - 10.6. IT Services which Integrate with the Participating Authority's Patient Administration System

### **SUBCATEGORY 3 – OUTSOURCING**

Lot 2 (Related Services) of this framework also requires provision for the supply of outsourced Angiography Services, as may be required by Participating authorities.

#### **Criteria 1: Outsourced Services**

11. A typical scenario is requirement to facilitate the capture of diagnostic images at a permanent location as chosen by the Participating Authority (which may be on or off the Participating Authority's site, not including mobile units).
12. All relevant standards set out in the Specification above under Subcategory 1 (Managed Services) and Subcategory 2 (Mobile Cardiac Catheterisation Laboratories), where applicable.
13. Where infrastructure is provided, fixtures and fittings should include (as a minimum):
  - 13.1. Air-conditioning;
  - 13.2. Heating;
  - 13.3. Lighting;
  - 13.4. Storage/lockers;
  - 13.5. Area/room designated for patient changing/preparation;
  - 13.6. Fire suppressants;
  - 13.7. Fire/smoke detectors and alarms;
  - 13.8. Patient alarm/call system;
  - 13.9. IT infrastructure including hardware and software; and
  - 13.10. Furniture (e.g. desk, chairs, clocks, bins etc)
14. Utilities and other facilities should include:
  - 14.1. Water/foul drainage where applicable;
  - 14.2. Power supply (suitable for connection to facility and/or standalone generator) where applicable;
  - 14.3. Uninterruptable power supply;
  - 14.4. Suitable cut-off switches (e.g. gas, electricity);
  - 14.5. Gas banks/storage where applicable;
  - 14.6. Where applicable suitable supply of medical/anaesthetic gases;
  - 14.7. Cat 5 or greater cabling for phone and internet;
  - 14.8. Suitably secure doors and windows; and
  - 14.9. Suitable 24-hour response maintenance and emergency cover
  - 14.10. General and clinical waste must be disposed of in line with the relevant legal procedures by the service provider

## **Criteria 2: Staffing**

15. Staffing provision **must** meet the following criteria:
  - 15.1. All staff **must** be suitably trained, experienced, and qualified
  - 15.2. (b) Clinical staff provided within this Lot **must** hold General Medical Council (GMC) registration
  - 15.3. All clinical staff **must** be CPD (Continuous Professional Development) certified
  - 15.4. All staff **must** have Disclosure and Barring Service (DBS) checks formally known as Criminal Records Bureau (CRB) completed
  - 15.5. Clinical staff **must** be trained in Basic Life Support (BLS) as a minimum
  - 15.6. Service Providers **must** be able to provide at least one contact name and number so that Participating authorities are able to resolve queries Monday-Friday between the hours of 9am-5pm
  - 15.7. A clinical service lead **must** be provided
  - 15.8. At least one member of staff (including Radiographers and any other clinical support staff) **must** be skilled and fully qualified in the operation of the (imaging) equipment

(PASS/FAIL)

## **Criteria 3: Outsourced Services – Training**

16. Any and all required training must be provided as an integral part of the Outsourced Service and should not attract an additional fee.
17. The Service Provider may be required to deliver training to the Participating Authority. If training is required, the Service provider must ensure that all training through the life of the agreement is delivered to ensure that all users are competent with the equipment and facilities provided;
  - 17.1. Contract Implementation Training: The Participating Authority must sign off to confirm that an acceptable level of user training has taken place.
  - 17.2. Ongoing/refresher Training: must be monitored throughout the life of the agreement during the management review meetings. Participating Authorities will inform the Service Provider where any ongoing/refresher training is required.
18. Service providers should be able to provide training to clinical engineering staff, if required.

## **Criteria 4: Outsourced Services – IT, Software & Integration**

19. Software & IT Integration may be required, as applicable on a case by case basis

20. Where IT / Integration is required, the Service Provider or any delegated sub-contractor must provide:
  - 20.1. all necessary hardware and software required to deliver the Service and provide these in a manner consistent with each Participating Authorities IT policies. This will include but is not limited to any back up and Disaster Recovery provision.
  - 20.2. Software and hardware supplied must meet any requirements set out by NHSE/I, NHSD or NHSx in terms of standards and specification to ensure integration with health systems.
  - 20.3. a secure and robust archive storage & retrieval solution based on the Participating Authority's record retention policy (This may extend up to 30 years).
  - 20.4. in accordance with each Participating Authority's IT policies, any and all associated support and maintenance required to ensure the optimal performance of the system whilst minimising / mitigating potential risk of downtime.
  
21. Where IT services are required, the Service provider may be required to provide additional IT services, including, but not limited to:
  - 21.1. Software and software upgrades
  - 21.2. IT integration
  - 21.3. Inventory Management Systems (operated both by Trust staff and Service Provider's staff)
  - 21.4. IT Services which Capture, record and upload current and future data items
  - 21.5. IT Services which Link to Electronic Patient Records
  - 21.6. IT Services which Integrate with the Participating Authority's Patient Administration System

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