National Framework Agreement for Teleradiology, Telepathology and Telemedicine Services

Project Reference: F/083/TSS/22/AB

SCHEDULE A

FRAMEWORK AGREEMENT SPECIFICATION

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1. Aims of the Framework Agreement

National demand on radiology services is increasing with the quantity of scans and required reports going up, whilst the number of radiologists is decreasing resulting in backlogs and pressure on existing staff. Teleradiology offers trusts an alternative to manage routine, urgent or specialist workload, and supports with the reduction of backlogs in care.

Teleradiology is the transmission of patients' radiological images between different locations for the production of a primary report, expert second opinion or clinical review. The different locations could be within the same organisation or in different organisations, within the same country or across international boundaries.

Telepathology is the electronic transmission of pathological images, usually derived from microscopes, from one location to another, for the purpose of interpretation and diagnosis.

Other areas of telemedicine are also becoming available, including but not limited to telemicrobiology and teledermatology. The scope of this agreement will include these and other specialties of telemedicine within a single lot to allow for expansion into new services during the term of the agreement, to help support the NHS with elective recovery and the NHS' core Key Performance Indicators and standards including but not limited to:

- A&E 4 hour wait targets;
- elective 18 week Referral to Treatment targets;
- cancelled procedures targets;
- bed availability and utilisation targets;
- timely and appropriate diagnostic testing targets;
- urgent 2 week GP referral rules for suspected cancer; and
- any core targets and standards introduced over the term of this framework.

Radiology workflow management systems are designed to improve productivity and efficiency in radiology departments. As business intelligence systems they allow precise forecasting of reporting capacity, enabling optimisation of departmental rotas and highlight areas for strategic recruitment based on supply and demand. These systems can reduce the costs of outsourcing and support radiology departments to operate as efficiently as possible.

Framework Agreement Lot Structure

The agreement will be split into three Lots:

- Lot 1 – Teleradiology and Telemedicine Services
- Lot 2 – Telepathology Services
- Lot 3 – Radiology Workflow Management Systems

The overall aims of the Services are to provide NHS Organisations with fully compliant solutions which supplement and support the delivery of patient care.

The Services will aim:

- To provide high quality support that can provide routine, specialist, urgent and/or backlog services in teleradiology, telepathology and/or other specialisms as required.
- To provide radiology workflow management systems to support the delivery of efficiencies in radiology departments.
- To prevent inappropriate waiting times for patients and assist NHS Organisations in meeting national targets and guidelines.
- To enable delivery of a patient pathway from referral to treatment that removes unnecessary delay in treatment.
- To establish a positive working relationship between an NHS Organisation and the Supplier to facilitate and maximise service delivery.

LOT 1 – TELERADIOLOGY AND TELEMEDICINE SERVICES

1. Teleradiology Services

1.1. The Supplier and its employees must comply with all relevant and current Information Governance Legislation and Regulations.

1.2. Teleradiology reporting services may be delivered either remotely or on-site.

1.3. All teleradiology services must be in line with Care Quality Commission guidelines and must be registered with the CQC, unless the Services are being delivered on a Participating Authority site.

1.4. The Supplier shall conform to all the stated CQC requirements at all times and specifically where this falls within the remit of the service provision that is being provided to the Participating Authority.

1.5. The Supplier must be able to offer routine, specialist, urgent and backlog reporting services. Participating Authorities may require one or more of these services at any one time.

1.6. Participating Authorities may require reporting services for one or more imaging modalities. Suppliers must provide an up-to-date list of all modalities they are able to cover.

1.7. Suppliers should be able to offer reporting services in a range of specialities and must provide an up-to-date list of all specialities they are able to cover. Specialities may include but are not limited to:

- Nuclear Medicine
- Fluoroscopy
- Oncology
- Neurological
- Paediatric
- Musculoskeletal
- Urology & Gynaecology
- Cardiac CT
- Thoracic
- Gastrointestinal

- CT Colonoscopy
- Stroke
- Polytrauma

1.8. The service provision must be available 24 hours per day, 7 days per week and 365 days per year.

1.9. At all times patients should benefit from the same quality of care as in the optimised hospital setting, and the Supplier is expected to support that.

1.10. The Supplier will commit to provide any information as reasonably required by the Participating Authority for the purposes of monitoring the Contracts awarded under the Framework.

1.11. Pricing offered under this agreement is fixed, varying for each modality, speciality, urgency of turnaround time and the quantity of regions under examination.

1.12. Suppliers are encouraged to develop innovative solutions to improve the Services offered to Participating Authorities under the Framework. These may include, but are not limited to, technology developments, innovations in workflow, teaching and learning opportunities, continuous improvement and the use of artificial intelligence (should this be approved for use by regulators). Use of such innovative solutions in any Contract must be agreed with the Participating Authority prior to their introduction into the Services under each Contract.

2. Report Production

2.1. The Supplier shall produce all Reports in accordance with all relevant and current Legislation, Regulations and Common Law.

2.2. The Supplier will ensure that all work in relation to the framework agreement is undertaken in line with all guidance and standards published by the Royal College of Radiologists.

2.3. All clinical personnel responsible for producing reports must be General Medical Council (GMC) registered, appear on the GMC Clinical Radiology Specialist Register, suitably qualified and experienced, and licensed.

2.4. The Supplier must ensure that all reporting staff are provided with the appropriate facilities and equipment to effectively carry out the duties required of them.

2.5. The Supplier will ensure that all reporting staff can access the relevant patient medical information, any prior images and/or reports provided and any laboratory or clinical test results to effectively perform the duties required of them.

2.6. The Supplier shall ensure that the Information System used or Radiology Information System ("RIS") fully integrates with the Participating Authority's Picture Archiving and Communications System ("PACS"), Electronic Patient Records system (EPR) or other system used as the case may be.

2.7. The Supplier must ensure that the Participating Authority can effectively transfer referrals, medical information, and images via the RIS, EPR and/or PACS or other information system as may be required in the execution of the Contract.

2.8. All reports should be provided within the maximum timescales agreed with the Participating Authority for that modality, type and complexity of report.

2.9. When a referral is made, a review should take place to ensure that the information provided is sufficient and detailed. Where it is not, more information must be sought prior to the report being made.

2.10. The reporting member of staff must cross-check the information contained within the referral against the medical history to confirm the identity of the patient, prevent errors in diagnosis and prevent breaches of data protection.

2.11. The reporting member of staff must ensure that all reports are checked for accuracy and that the information is explicit and written in a way that the referrer can understand. Where the Participating Authority requires further clarification regarding the contents of a report, the reporting member of staff should provide the information in accordance with the timescales agreed with the Participating Authority prior to the commencement of the Contract.

2.12. All reports produced by reporting staff should include, as a minimum:
2.12.1. clinical details relevant to the patient case; and
2.12.2. a full description of the examination; and
2.12.3. record of any relevant verbal or written communications between the reporting member of staff and the referrer pertinent to the examination; and
2.12.4. a conclusion or interpretation of the findings in a clinical context.

2.13. All reports must clearly identify the member of staff that interpreted the examination and created the report.

2.14. The reporting member of staff may be required to communicate via telephone or other mechanisms to ensure that the referrer receives the necessary feedback when the usual methods of report transmission could lead to delays in treatment. Urgent communication may also be required to prevent potential harm to others (e.g. where there is evidence of infectious disease). The reporting member of staff should ensure that details of all communications are recorded in the final report before issuing to the referrer to comply with the local flagging methodology for identification of unexpected findings (e.g. cancer), of the Participating Authority.

2.15. Reporting radiologists may be required to attend multidisciplinary meetings from time to time. Attendance may be virtual and will be confirmed and agreed with the Participating Authority where required.

2.16. For the avoidance of doubt, innovations including but not limited to the use of Artificial Intelligence (AI) in the triaging of referrals and/or in diagnosis and/or other elements of the Service is included in the scope of the framework agreement. Any use of such innovations must be expressly agreed with the Participating Authority.

3. Reporting Capacity

3.1. The Participating Authority shall, where possible, provide the Supplier with a weekly or monthly forecast of expected service requests levels to enable the Supplier to effectively assess capacity of internal resources for the week or month ahead.

3.2. Using the forecasts provided, the Supplier shall confirm the reporting capacity available to the Participating Authority for the week ahead, also confirming its ability to meet expected turnaround times.

3.3. It is anticipated that the percentage of reports delivered within agreed timescales will form a Key Performance Indicator in call-off contracts awarded under this framework agreement. Target percentages should be agreed with the Participating Authority during Contract Implementation.

4. Classification of Services

4.1. Classification, Modalities and Response Times

Classification	Response Time for Delivery of Report	Modality/ Sub-speciality
Urgent Day	4 Hour	Plain Film
Urgent Day	4 Hour	CT
Urgent Day	4 Hour	MRI
Emergency	30 Minutes	Stroke
Emergency	60 Minutes	Polytrauma
Emergency	60 Minutes	Plain Film
Emergency	60 Minutes	CT
Emergency	60 Minutes	MRI
Routine	24 Hours	Plain Film
Routine	48 Hours	Plain Film
Routine	72 Hours	Plain Film
Routine	96 Hours	Plain Film
Routine	120 Hours	Plain Film
Routine	24 Hours	CT
Routine	48 Hours	CT
Routine	72 Hours	CT
Routine	96 Hours	CT
Routine	120 Hours	CT
Routine	24 Hours	MRI
Routine	48 Hours	MRI
Routine	72 Hours	MRI
Routine	96 Hours	MRI
Routine	120 Hours	MRI
Specialist / Complex	48 Hours	CT
Specialist / Complex	72 Hours	CT
Specialist / Complex	96 Hours	CT
Specialist / Complex	120 Hours	CT
Specialist / Complex	48 Hours	MRI
Specialist / Complex	72 Hours	MRI
Specialist / Complex	96 Hours	MRI

Specialist / Complex	120 Hours	MRI
Specialist / Complex	72 Hours	PET CT
Specialist / Complex	96 Hours	PET CT
Specialist / Complex	120 Hours	PET CT
Specialist / Complex	72 Hours	Nuclear Medicine
Specialist / Complex	96 Hours	Nuclear Medicine
Specialist / Complex	120 Hours	Nuclear Medicine
Specialist / Complex	72 Hours	CT Colonoscopy
Specialist / Complex	96 Hours	CT Colonoscopy
Specialist / Complex	120 Hours	CT Colonoscopy
Specialist / Complex	72 Hours	Breast MRI / Mammography
Specialist / Complex	96 Hours	Breast MRI / Mammography
Specialist / Complex	120 Hours	Breast MRI / Mammography
Backlog Reporting	7 Days	Plain Film
Backlog Reporting	7 Days	CT
Backlog Reporting	7 Days	MRI

4.2. The information provided in the above table is not an exhaustive list of modalities that may be provided. Further specific radiology or diagnostic reporting requirements may be requested by the Participating Authority.

4.3. The response times listed above are maximum response times for each report, and Suppliers must deliver reports within these stated timescales. Reduced timescales for one or more report types, or for an agreed proportion of reports, may be agreed with the Participating Authority at call-off contract stage.

4.4. The Supplier is responsible for assessing the nature of the referral received by the referrer along with any case notes and medical information and, in accordance with the above table and the agreed Commercial Schedule, shall categorise the services required before allocating the referral to the reporting member of staff.

4.5. Where there is a difference in the categorisation of the referral between the referrer and the Supplier, this should be highlighted to the referrer at the earliest opportunity.

4.6. Routine services include the reporting of images that have been deemed, by the referrer and/or the appointed Radiologist, as non-urgent, inconsequential in nature and non-life threatening.

4.7. The hours during which routine diagnostic and reporting services shall be undertaken will be agreed with the Participating Authority at Contract Implementation.

4.8. Urgent Day diagnostic and reporting services are those classified as referrals which may potentially be life threatening, resulting in mortality or unnecessary morbidity if not appropriately handled, but are undertaken during standard business hours.

4.9. The maximum turnaround time for Urgent Day services shall be 4 hours, unless otherwise agreed with the Participating Authority during the initial Contract Implementation meeting.

4.10. Emergency diagnostic and reporting services reporting are those referrals which may potentially be life threatening, resulting in mortality or unnecessary morbidity if not appropriately handled, and are undertaken outside of Standard Business Hours.

4.11. The maximum turnaround time for Emergency services shall be 60 minutes, with the exception of any referral relating to a suspected stroke patient. The maximum turnaround time for stroke referrals shall be 30 minutes, in accordance with NICE guidelines.

4.12. Emergency services may be required either during standard business hours, or out of hours.

4.13. Specialist/Complex services refers to the complexity of the modality and sub-specialty of the referral whereby the diagnostic and reporting service requires the use of a specialist Radiology Consultant (e.g. Oncology). The definition of complex services may vary depending on the requirements of the Participating Authority and will be determined at Contract Implementation.

4.14. Backlog services refer to the diagnostic and reporting services for non-urgent, routine referrals that do not require a turnaround time of less than 120 Hours (5 calendar days). The maximum turnaround time for Backlog services shall be 168 Hours (7 calendar days) unless a longer period of time is deemed acceptable by the Participating Authority and contract pricing has been agreed by both parties in advance of the commencement of the provision of the services.

5. Audit

5.1. The Supplier shall, for the lifetime of the Framework Agreement and any Contracts awarded underneath it, conduct internal audits to assess compliance with sector standards, quality assurance and the performance of the reporting members of staff in the provision of the services.

5.2. The Supplier shall either appoint an in-house experienced and qualified Responsible Officer or utilise the services of an external independent auditing organisation to conduct the audits.

5.3. A percentage of reports must be audited each week, along with spot checks on each reporting member of staff. Percentages and regularity of spot checks may be agreed with the Participating Authority at Contract Implementation.

5.4. On request, the Supplier must share the outcome of these audits with the Participating Authority at any time throughout the duration of the Contract.

6. Telemedicine Services

6.1. The Supplier and its employees must comply with all relevant and current Information Governance Legislation and Regulations.

6.2. All telemedicine services must be in line with Care Quality Commission guidelines and must be registered with the CQC, unless they are being performed on a Participating Authority site.

6.3. The Supplier shall conform to all the stated CQC requirements at all times and specifically where this falls within the remit of the service provision that is being provided to the Participating Authority.

6.4. The Supplier must be able to offer a range of services for the speciality that they provide. Participating Authorities may require one or more of these services at any one time.

6.5. Suppliers must provide an up-to-date list of all specialities they are able to cover, including details of any sub-specialties available.

6.6. The service provision should be available 24 hours per day, 7 days per week and 365 days per year.

6.7. The Supplier will commit to provide any information as reasonably required by the Participating Authority for the purposes of monitoring the Contracts awarded under the Framework.

6.8. Suppliers are encouraged to develop innovative solutions to improve the Services offered to Participating Authorities under the Framework. These may include, but are not limited to, technology developments, innovations in workflow, teaching and learning opportunities, continuous improvement and the use of artificial intelligence (should this be approved for use by regulators). Use of such innovative solutions in any Contract must be agreed with the Participating Authority prior to their introduction into the Services under each Contract.

7. Report Production

7.1. The Supplier shall produce all Reports in accordance with all relevant and current Legislation, Regulations and Common Law.

7.2. The Supplier will ensure that all work in relation to the framework agreement is undertaken in line with all guidance and standards published by the appropriate national and/or regulatory body and/or Royal College for the area of medicine that they are working in.

7.3. All clinical personnel responsible for producing reports must be General Medical Council (GMC) registered, suitably qualified, experienced, professionally registered, and licensed.

7.4. The Supplier must ensure that all reporting staff are provided with the appropriate facilities and equipment to effectively carry out the duties required of them.

7.5. The Supplier will ensure that all reporting staff can access the relevant patient medical information, any prior images and/or reports provided and any laboratory or clinical test results to effectively perform the duties required of them.

7.6. The Supplier shall ensure that the Information System used fully integrates with the Participating Authority's Picture Archiving and Communications System ("PACS"), Electronic Patient Records system (EPR) or other system used as the case may be.

7.7. The Supplier must ensure that the Participating Authority can effectively transfer referrals, medical information, and images via their Information System such as RIS,

EPR and/or PACS or other information system as may be required in the execution of the Contract.

7.8. All reports should be provided within the maximum timescales agreed with the Participating Authority for that specialty, type and complexity of report.

7.9. When a referral is made, a review should take place to ensure that the information provided is sufficient and detailed. Where it is not, more information must be sought prior to the report being made.

7.10. The reporting member of staff must cross-check the information contained within the referral against the medical history to confirm the identity of the patient, prevent errors in diagnosis and prevent breaches of data protection.

7.11. The reporting member of staff must ensure that all reports are checked for accuracy and that the information is explicit and written in a way that the referrer can understand. Where the Participating Authority requires further clarification regarding the contents of a report, the reporting member of staff should provide the information in accordance with the timescales agreed with the Participating Authority prior to the commencement of the Contract.

7.12. All reports produced by reporting staff should include, as a minimum:
- 7.12.1. clinical details relevant to the patient case; and
- 7.12.2. a full description of the examination; and
- 7.12.3. record of any relevant verbal or written communications between the reporting member of staff and the referrer pertinent to the examination; and
- 7.12.4. a conclusion or interpretation of the findings in a clinical context.

7.13. The reporting member of staff may be required to communicate via telephone or other mechanisms to ensure that the referrer receives the necessary feedback when the usual methods of report transmission could lead to delays in treatment. Urgent communication may also be required to prevent potential harm to others (e.g. where there is evidence of infectious disease). The reporting member of staff should ensure that details of all communications are recorded in the final report before issuing to the referrer to comply with the local flagging methodology for identification of unexpected findings (e.g. cancer), of the Participating Authority.

7.14. Reporting staff may be required to attend multidisciplinary meetings from time to time. Attendance may be virtual, and will be confirmed and agreed with the Participating Authority where required.

7.15. For the avoidance of doubt, innovations including but not limited to the use of Artificial Intelligence (AI) in the triaging of referrals and/or in diagnosis and/or other elements of the Service is included in the scope of the framework agreement. Any use of such innovations must be expressly agreed with the Participating Authority.

8. Reporting Capacity

8.1. The Participating Authority shall, where possible, provide the Supplier with a weekly or monthly forecast of expected service requests levels to enable the Supplier to effectively assess capacity of internal resources for the week or month ahead.

8.2. Using the forecasts provided, the Supplier shall confirm the reporting capacity available to the Participating Authority for the week ahead, also confirming its ability to meet expected turnaround times.

8.3. It is anticipated that the percentage of reports delivered within agreed timescales will form a Key Performance Indicator in call-off contracts awarded under this framework agreement. Target percentages should be agreed with the Participating Authority during Contract Implementation.

9. Classification of Services

9.1. Classification and Response Times

Classification	Response Time for Delivery of Report
Routine	24 Hours
Routine	48 Hours
Routine	72 Hours
Routine	120 Hours
Routine	7 days
Urgent	4 Hours
Urgent	24 Hours
Urgent	48 Hours
Specialist / Complex	4 Hours
Specialist / Complex	24 Hours
Specialist / Complex	48 Hours
Specialist / Complex	72 Hours
Specialist / Complex	120 Hours
Specialist / Complex	7 days

9.2. The information in the above table is provided as guidance and should not be considered an exhaustive list. Final definitions and reporting timescales should be agreed with the Participating Authority at Contract Implementation.

9.3. The Supplier is responsible for assessing the nature of the referral received by the referrer along with any case notes and medical information and, in accordance with the above table and the agreed Commercial Schedule, shall categorise the services required before allocating the referral to the reporting member of staff.

9.4. Where there is a difference in the categorisation of the referral between the referrer and the Supplier, this should be highlighted to the referrer at the earliest opportunity.

9.5. Routine services include the reporting of images that have been deemed, by the referrer and/or the appointed specialist, as non-urgent, inconsequential in nature and non-life threatening.

9.6. Routine services shall be undertaken during standard business hours.

9.7. Urgent services are those classified as referrals which may potentially be life threatening, resulting in mortality or unnecessary morbidity if not appropriately handled, but are undertaken during standard business hours.

9.8. Specialist/Complex services refers to the complexity of the requirement and sub-specialty of the referral whereby the service requires the use of a specialist Consultant. The definition of complex services may vary depending on the requirements of the Participating Authority and will be determined at Contract Implementation.

10. Audit

10.1. The Supplier shall, for the lifetime of the Framework Agreement and any Contracts awarded underneath it, conduct internal audits to assess compliance with sector standards, quality assurance and the performance of the members of staff in the provision of the services.

10.2. The Supplier shall either appoint an in-house experienced and qualified Responsible Officer or utilise the services of an external independent auditing organisation to conduct the audits.

10.3. A percentage of reports must be audited each week, along with spot checks on each reporting member of staff. Percentages and regularity of spot checks may be agreed with the Participating Authority at Contract Implementation.

10.4. On request, the Supplier must share the outcome of these audits with the Participating Authority at any time throughout the duration of the Contract.

11. Implementation

11.1. The Supplier must operate a defined and documented quality management system to the standard of EN ISO 9001:2008, EN ISO 13485:2016, or an equivalent recognised standard.

11.2. Contract Implementation Plans may be required for each Contract under this Framework (preferably in Gantt chart format); these will reflect the planned procedure of smooth handover from the incumbent provider to the successful provider, including a Data Protection Impact Assessment.

11.3. The Contract Implementation Plan will outline the following:

11.3.1. Details of all key internal stakeholders who will represent the Supplier during the implementation process, including identifying one individual responsible for managing the implementation to conclusion and will be the principal contact for the Participating Authority during implementation.

11.3.2. Identify all key decision makers involved in the implementation of the Contract at the Participating Authority.

11.3.3. The co-ordination of any sub-contracting arrangements required to fully service the Contract as specified.

11.3.4. Specific, achievable target dates for each stage of the implementation including a final date for the conclusion of the Contract Implementation Plan and the commencement of the Services. Where sub-contracting arrangements are required to fully service the Contract as specified, the co-ordination of these will be laid out in the Contract Implementation Plan.

11.4. The Implementation Plan provided by the Supplier is subject to alteration and agreement with the Participating Authority(s).

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

11.6. The Supplier will attend an initial engagement meeting with the Participating Authority.

11.7. The required frequency of operational, contractual and monitoring meetings between the Supplier and Participating Authority will be agreed at implementation stage.

11.8. The Supplier will achieve value for money and continuous improvement which will be measured by Key Performance Indicators agreed with the Participating Authority. Key Performance Indicators may include but not be restricted to:

11.8.1. Improved times to treatment

11.8.2. The percentage of reports delivered within the agreed timescales for each classification and modality required

11.8.3. The number of reports requested each period

11.8.4. The number of reports audited each period, and the percentage that were compliant

11.9. The Supplier and the Participating Authority must agree who retains responsibility for the care of the patient, and this must be clearly stated in the Contract.

12. Training

12.1. Where required, the Supplier must provide comprehensive training to employees of the Participating Authority on how to use all elements of the Services as relevant to the requirements of the Participating Authority. The training will be provided free of charge.

12.2. Training should be provided for all employees of the Participating Authority who require it.

12.3. Training may be in the following methods: face to face (group or individual), videoconference, tele-conference, email, and literature guidance.

12.4. Training will be planned and provided as part of the Contract Implementation Plan and must be provided prior to the commencement of the Services.

12.5. The Supplier will provide additional ad-hoc support and training throughout the Term of the Call-Off Contract as reasonably required by the Participating Authority.

12.6. The Supplier will provide additional training to new employees of the Participating Authority if required.

12.7. The Supplier will provide additional training as a result of a change or update to the Services if this is required.

12.8. Should training be required for an element of the services provided by a subcontractor, the Supplier must organise for this training to be carried out in accordance with the Training requirements within this Specification.

13. Transition

13.1. The Supplier will work closely with the Participating Authority to produce a detailed exit plan for the end of each Contract called off from the Framework Agreement.

13.2. In the event of the termination or expiry of the Contract, the Supplier will work co-operatively with the Participating Authority and/or the incoming Supplier to ensure smooth transition to the new Supplier.

13.3. The Supplier will provide a detailed exit plan during contract implementation for review and approval by the Participating Authority.

13.4. There will be no costs incurred by any Participating Authority with respect to the termination or expiry of the contract.

14. Service Management

14.1. The service will ensure it is compliant with all relevant NICE and DHSC good practice and guidance as well as all locally agreed policies and guidance.

14.2. The service will facilitate discussions with stakeholders and, wherever possible, engage in collaborative working for the benefit of patients.

14.3. The service will maximise the use of new innovations and technology where evidence-based.

14.4. Where optimal technologies are not currently available it is expected that the Supplier will move towards new ways of working during the lifetime of the Framework Agreement and any Contracts awarded under it.

14.5. The Supplier will ensure they have robust business continuity plans in place to ensure continued service is provided to patients in the event of disruption, which could include loss of power, IT, staff sickness, strikes, adverse weather including snow, flood etc.

14.6. The Supplier shall maintain standard Business Hours as a minimum, which are a minimum of 8 hours between the hours of 8:00am and 6:00pm, Monday to Friday.

14.7. The Supplier shall also provide an ‘Out of Hours’ customer service helpdesk to ensure continuity of the provision of Services, this may be a telephone service desk or email inbox.

14.8. The Supplier will be expected to implement a set of policies relating to customer service, employee etiquette and Service availability. These will be agreed with the Participating Authority at Contract Implementation. The Supplier may be required upon request to produce evidence demonstrating that adherence to the policies has been monitored and recorded.

14.9. The Supplier must provide each Participating Authority with a named dedicated account manager who will be the single point of contact for the duration of the Contract.

15. Data Protection and Information Management

15.1. The Supplier(s) must comply with, and operate in accordance with, the most recent regulations regarding data sharing and transfer.

15.2. The Supplier must operate a defined and documented information security management system such as EN ISO 27001:2013, or an equivalent recognised standard.

15.3. The Supplier must comply with the Data Protection Act 2018 and should demonstrate compliance with the General Data Protection Regulations (GDPR).

15.4. The Supplier must evidence an audit trail of personnel accessing patient identifiable data, as and when requested.

15.5. The Supplier must have a robust policy in place that details the management of patient data, information storage, disposal, and disaster recovery of data.

15.6. The Supplier must have the capability to provide reports via a secure network portal.

15.7. The portal must ensure the secure and protected transfer of patient data, reporting and communications between the systems of the Supplier and the Participating Authority. The portal must record fully, including user identification, all instances of personnel accessing patient identifiable data and sensitive information.

15.7.The Supplier must adhere to the IT policy, data management and security policies of each individual Participating Authority, the details of which will be agreed at Contract Implementation.

16. **Clinical Governance**

16.1. The Supplier must commit to comply with any Participating Authority's policies and procedures appropriate to the performance of the Services, including but not restricted to clinical governance policies and risk management strategies. These may be developed between the Supplier and the Participating Authority to ensure that they are relevant to the service and appropriate for the service level being provided. Participating Authorities will provide relevant policies to the Supplier as necessary or upon written request.

16.2. The Supplier must have robust, clearly defined and auditable quality assurance processes to ensure that Services are carried out to the satisfaction of any Participating Authority that chooses to contract with the Supplier for the services covered by this Framework which will ensure:

16.2.1. Adherence to the Participating Authority's Policies and Procedures

16.2.2. All requirements relating to health and safety in the workplace are satisfied

16.2.3. Professionals are appropriately trained and competent to perform duties required of their role

16.3. The Supplier must have a robust, clearly defined and auditable information system security management system to protect Patient data.

16.4. The Supplier must operate within Care Quality Commission (CQC) System Guidelines and the guidelines outlined within the Participating Authority's own Standard Operating Procedures throughout the life of the Agreement and during any Contract whose performance concludes outside the period of the Framework Agreement.

16.5. The Supplier will implement specific audit arrangements and submit evaluation of audits to the Framework Manager or to any Participating Authority on request.

16.6. Topics for audit will be agreed between the Participating Authority and the Supplier and will be detailed in tailored agendas for review meetings. The Supplier will ensure

attendance at such meetings by an appropriately senior officer of the Supplier who will be named within the Call Off Contract.

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

16.8. The Supplier must have a robust system in place for reporting patient safety incidents and reviewing of this data at appropriate levels.

16.9. The Supplier will investigate and manage Serious Untoward Incidents and complaints in line with the agreed complaints and incident reporting procedures, implementing the NHS Commissioning Board Special Health Authority (formerly NPSA) investigation toolkit (or the procedures of equivalent organisations in Scotland, Wales and Northern Ireland, where applicable).

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

16.11. Suppliers must comply with any statutory duty of candour to patients.

16.12. Reporting staff must hold adequate individual insurance and indemnity cover for all of their patients, regardless of location. The Supplier must ensure they have adequate medico-legal and insurance cover.

16.13. If the Supplier carries out Regulated Activities as described in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (and as amended) and none of the permitted exemptions apply then the Supplier must hold, and maintain for the duration of the period in which the Regulated Activities are carried out, appropriate registration with the Care Quality Commission (for Regulated Activities in carried out in England), Healthcare Inspectorate Wales (for Regulated Activities in carried out in Wales), Healthcare Improvement Scotland (for Regulated Activities in carried out in Scotland) or The Regulation and Quality Improvement Authority (for Regulated Activities in carried out in Northern Ireland), or with any successor to any of these organisations, as appropriate.

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

17. **Corporate Governance**

17.1. The Supplier will be responsible for:

17.1.1. Delivering the services in the agreed service environment

17.1.2. Leadership of their clinical team

17.1.3. Provision of clinical guidance and support where necessary to ensure that their staff work to a clinical governance framework

17.1.4. Ensuring that all staff are competent to perform all duties that are required of their role

17.1.5. Access to relevant training and Continuous Professional Development (CPD) for clinical and non-clinical staff

17.1.6. Leading in audit, service evaluation and service development

17.2. The Supplier must have robust, auditable management and corporate governance procedures including clear responsibilities for all staff and appropriate employment policies and procedures, insurances and indemnities and, where relevant, clear written agreements with sub-contractors.

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

17.4. The Supplier must comply with the following:

17.4.1. Data Protection Act 2018

17.4.2. Caldicott Guidelines 1997

17.4.3. The relevant requirements of the Access to Health Records Act 1990

17.4.4. Access to Medical Reports Act 1988

17.4.5. Confidentiality Code of Practice 1998

17.4.6. The relevant requirements of the Care Standards Act 2000

17.4.7. Any other relevant statutory requirements.

17.4.8. Any amendments to the above.

17.5. The Supplier must be registered with the Information Commissioners Office as a Data Processer.

17.6. Patient records will remain the responsibility of the Participating Authority. The Supplier shall obtain no proprietary interest in any patient data and shall ensure the return of any material detailing or recording such patient data to the Participating Authority on demand.

17.7. The Supplier will ensure that all patients' case notes are kept securely and transferred to the Supplier securely where the Supplier needs such notes to perform its duties under the terms of the contracted service.

17.8. The Supplier shall ensure that all staff engaged to undertake any of the services fulfil all statutory requirements of employment including but not limited to the right to work in the UK.

17.9. The Supplier must conduct all pre-employment checks in accordance with the NHS Employment Check Standards. The NHS Employment Check Standards apply to permanent staff, staff on fixed-term contracts, temporary staff, volunteers, students, trainees, contractors and highly mobile staff employed directly by the NHS, by an agency or by any third-party employing staff who will provide Services into the NHS.

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

17.11. The Supplier shall take all reasonable steps to ensure that no Participating Authority is exposed to any liabilities resulting from any part of the services being determined by HM Revenue and Customs as disguised employment as defined in 2017 Public Sector Contracting ("IR35") regulations.

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

17.13. Patients for whom reports are produced services will remain the overall responsibility of the Participating Authority and as such will be covered by each Participating Authority's NHS Resolution insurances. The Participating Authority will ensure that NHS Resolution is notified of the new sub-contract arrangements for the services. The Supplier must ensure that it retains all appropriate public liability, professional liability and employer liability insurance at all times throughout the life of the Agreement and during any treatments whose performance concludes outside the period of the Framework Agreement.

17.14. The Supplier shall produce to the Framework Manager or to any Participating Authority on request documentary evidence that the insurance required is properly maintained.

17.15. The Supplier will maintain a complaints procedure in line with applicable law and provide as and when necessary details of such a procedure to the Framework Manager or to any Participating Authority.

17.16. Where the Participating Authority wishes to make a complaint about the Supplier or an individual employee or any other element covered by the scope of the Services, the Supplier shall operate a clear and written procedure for handling such complaints.

17.17. The Supplier shall inform the Framework Manager of any complaints made by any Participating Authority and supply copies of all correspondence to the Framework Manager which relates to complaints or the handling of them.

17.18. In the event that complaints regarding the services are made by patients to a Participating Authority, the Participating Authority will forthwith inform the Supplier and supply relevant correspondence.

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

17.19.1. Appoint a complaints manager or individual with complaints remit

17.19.2. Provide the Framework Manager and any Participating Authority with relevant details of the complaints manager

17.20. The Supplier will undertake where requested to provide information to the Participating Authority to support the Participating Authority's adherence to national or local frameworks for performance reporting.

17.21. The Supplier will collect and provide anonymised data to the Participating Authority for assessment of Patient Reported Outcome Measures.

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

17.23. The Supplier must comply with all current and future Legislation and Regulations applicable to the transfer of data outside of the United Kingdom. The Supplier may be required to provide evidence, upon request, demonstrating compliance to these mandatory requirements through the lifetime of the Framework and any subsequent Call-Off Contracts with the Participating Authority.

17.24. If the Supplier deploys, in the provision of the Services, reporting members of staff located outside of the United Kingdom and doing so results in the international transfer of personal or sensitive data, this shall be subject to approval by the Framework Manager and the Participating Authority who require notification of this activity prior to the commencement of the Services.

17.25. The Supplier shall ensure that all staff engaged to undertake any of the services fulfil all statutory requirements of employment including but not limited to the right to work in the UK.

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

18. **Registration and Standards**

18.1. If the Supplier is providing remote teleradiology Services, the Supplier must be registered with the Regulatory Body, Care Quality Commission (or equivalent Regulatory Body depending on the region of the Participating Authority) and shall be subject to its regulations and standards. Registration must be maintained throughout the term of the Framework Agreement and any Contracts awarded underneath it.

18.2. The Supplier must demonstrate compliance to the standards on image and report sharing and patient safety. This should include, but not be limited to;

18.2.1. Data Security and Protection Toolkit Statement of Compliance

18.2.2. service delivery through a secure network portal

18.2.3. diagnostic workstations must have a minimum standard of 2MP

18.2.4. use of a full PACS workstation for all Reporting

18.2.5. EURATOM 97/43 Directive

18.2.6. European Working Time Directive

18.3. It is preferable for the Supplier to hold a current Quality Standard for Imaging accreditation (QSI), which has been licensed by UKAS.

18.4. The Supplier must hold and maintain Cyber Security Essentials Plus accreditation throughout the period of the Framework Agreement and any Contract called off from the Framework Agreement.

LOT 2 – TELEPATHOLOGY SERVICES

1. Telepathology Services

1.1. The Supplier and its employees must comply with all relevant and current Information Governance Legislation and Regulations.

1.2. All remote pathology services must be in line with Care Quality Commission guidelines and must be registered with the CQC.

1.3. The Supplier shall conform to all the stated CQC requirements at all times and specifically where this falls within the remit of the service provision that is being provided to the Participating Authority.

1.4. The Supplier must be able to offer primary reporting and secondary consultation as a minimum. Participating Authorities may require one or more of these services at any one time.

1.5. Suppliers should be able to offer reporting services in a range of specialities and must provide an up-to-date list of all specialities they are able to cover. Specialities may include but are not limited to:

- Gastrointestinal
- Skin
- Genitourinary
- Bone and soft tissue
- Liver
- Lung
- Breast
- Gynaecology (including placenta)
- Head and neck
- Cardiovascular
- Neuropathology
- Medical renal pathology
- Endocrine
- Oral pathology

1.6. The hours of service provision will be agreed with the Participating Authority at Contract Implementation stage.

1.7. The Supplier will commit to provide any information as reasonably required by the Participating Authority for the purposes of monitoring the Contracts awarded under the Framework.

1.8. Pricing offered under this agreement is fixed, varying with the complexity of the sample type under examination, and whether a primary diagnosis or secondary consult is required.

1.9. Suppliers are encouraged to develop innovative solutions to improve the Services offered to Participating Authorities under the Framework. These may include, but are not limited to, technology developments, innovations in workflow, teaching and learning opportunities, continuous improvement and the use of artificial intelligence (should this be approved for use by regulators). Use of such innovative solutions in

any Contract must be agreed with the Participating Authority prior to their introduction into the Services under each Contract.

2. Report Production

2.1. The Supplier shall produce all Reports in accordance with all relevant and current Legislation, Regulations and Common Law.

2.2. All Reports must clearly state that diagnosis is based on off-site review of the images.

2.3. The Supplier will ensure that all work in relation to the framework agreement is undertaken in line with all guidance and standards published by the Royal College of Pathologists.

2.4. All clinical personnel responsible for producing reports must be General Medical Council (GMC) registered, suitably qualified, experienced, professionally registered, and licensed.

2.5. The technical specifications of the displays (including luminance, resolution and contrast ratio) used by reporting staff must be sufficient to ensure an accurate diagnosis. In the absence of an equivalent pathology imaging standard to the DICOM 3.14 standard used for radiology all Suppliers should ensure their reporting staff have access to displays that meet or exceed the following specifications.

Colour Gamut	>=100% of sRGB
Peak Brightness	>=250 Cd/m2
Contrast ratio	>=1000:1
Colour depth	8 bit

NB: If 10-bit (aka HDR) displays are used by reporting staff they must match these specifications when set to an 8 bit colour depth to align with the 8-bit colour depth of the digital slides. Use of a 10 bit display mode by reporting staff is not permitted as the conversion from 8 bit colour depth to 10 bit colour depth may induce errors in the displayed image

2.6. Where virtual slides are being used as part of the Service, the Supplier must ensure that the network capacity and/or bandwidth is sufficient to support this.

2.7. Care must be taken in the production of digital slides to ensure sufficient image quality is captured. Robust quality control procedures must be in place to minimise the incidence of sub-optimal digital slides.

2.8. The Supplier will ensure that all reporting staff can access the relevant patient medical information, any prior images and/or reports provided and any laboratory or clinical test results to effectively perform the duties required of them.

2.9. The Participating Authority may require that the Supplier's systems integrate with their own. This will be agreed at Contract Implementation stage.

2.10. The Supplier must ensure that there is a secure and effective method for the Participating Authority to effectively transfer referrals, medical information, and images that may be required in the execution of the Contract.

2.11. All reports should be provided within the maximum timescales agreed with the Participating Authority for that sub-specialty, type and complexity of report.

2.12. When a referral is made, a review should take place to ensure that the information provided is sufficient and detailed. Where it is not, more information must be sought prior to the report being made.

2.13. For large, complex and/or unusual specimens, close collaboration may be required between remote reporting staff and laboratory staff. Gross photographs should be made available by laboratory staff in these circumstances.

2.14. The reporting member of staff must cross-check the information contained within the referral against the medical history to confirm the identity of the patient, prevent errors in diagnosis and prevent breaches of data protection.

2.15. The reporting member of staff must ensure that all reports are checked for accuracy and that the information is explicit and written in a way that the referrer can understand. Where the Participating Authority requires further clarification regarding the contents of a report, the reporting member of staff should provide the information in accordance with the timescales agreed with the Participating Authority prior to the commencement of the Contract.

2.16. All reports produced by reporting staff should include, as a minimum:
- 2.16.1. clinical details relevant to the patient case; and
- 2.16.2. a full description of the examination; and
- 2.16.3. record of any relevant verbal or written communications between the reporting member of staff and the referrer pertinent to the examination; and
- 2.16.4. a conclusion or interpretation of the findings in a clinical context.

2.17. The reporting member of staff may be required to communicate via telephone or other mechanisms to ensure that the referrer receives the necessary feedback for example when the usual methods of report transmission could lead to delays in treatment, or if it is required to request a re-scanning of a slide. Urgent communication may also be required to prevent potential harm to others (e.g. where there is evidence of infectious disease). The reporting member of staff should ensure that details of all communications are recorded in the final report before issuing to the referrer to comply with the local flagging methodology for identification of unexpected findings (e.g. cancer), of the Participating Authority.

2.18. For the avoidance of doubt, innovations including but not limited to the use of Artificial Intelligence (AI) in the triaging of referrals and/or in diagnosis and/or other elements of the Service is included in the scope of the framework agreement. Any use of such innovations must be expressly agreed with the Participating Authority.

3. Reporting Capacity

3.1. The Participating Authority shall, where possible, provide the Supplier with a weekly or monthly forecast of expected service requests levels to enable the Supplier to effectively assess capacity of internal resources for the week or month ahead.

3.2. Using the forecasts provided, the Supplier shall confirm the reporting capacity available to the Participating Authority for the week ahead, also confirming its ability to meet expected turnaround times.

3.3. It is anticipated that the percentage of reports delivered within agreed timescales will form a Key Performance Indicator in call-off contracts awarded under this framework agreement. Target percentages should be agreed with the Participating Authority during Contract Implementation.

4. Classification of Services

4.1. Classification and Response Times

Classification	Response Time for Delivery of Report
Primary Diagnosis	5-7 working days
Secondary Consult	7-10 working days

4.2. The response times listed above are maximum response times for each report, and Suppliers must deliver reports within these stated timescales. Reduced timescales for one or more report types, or for an agreed proportion of reports, may be agreed with the Participating Authority at call-off contract stage.

4.3. Primary Diagnostic services refer to the reporting of cases that have not been seen by any other pathologist, so the Supplier is providing the primary report of a particular case.

4.4. Secondary Consult services are where a pathologist, clinician or patient from a hospital requires and/or requests a second opinion on a particular case from a recognized sub-specialist Histopathologist. This is usually to provide a more definitive diagnosis, resolve a contentious issue, provide reassurance and confirmation of the original diagnosis and/or refine the original or primary pathology report.

5. Audit

5.1. The Supplier shall, for the lifetime of the Framework Agreement and any Contracts awarded underneath it, conduct internal audits to assess compliance with sector standards, quality assurance and the performance of the reporting members of staff in the provision of the services.

5.2. Audits must include quality assessment of the following areas: turnaround times, content of reports, layout/format, accuracy, conformance to practice guidelines and clinical utility.

5.3. The Supplier shall either appoint an in-house experienced and qualified Responsible Officer or utilise the services of an external independent auditing organisation to conduct the audits.

5.4. A minimum of 5% of reports must be audited each week; the actual percentage of reports audited be agreed with the Participating Authority at Contract Implementation.

5.5. On request, the Supplier must share the outcome of these audits with the Participating Authority at any time throughout the duration of the Contract.

6. Implementation

6.1. The Supplier must operate a defined and documented quality management system to the standard of EN ISO 9001:2008, EN ISO 13485:2016, or an equivalent recognised standard.

6.2. Contract Implementation Plans may be required for each Contract under this Framework (preferably in Gantt chart format); these will reflect the planned procedure of smooth handover from the incumbent provider to the successful provider, including a Data Protection Impact Assessment.

6.3. The Contract Implementation Plan will outline the following:

6.3.1. Details of all key internal stakeholders who will represent the Supplier during the implementation process, including identifying one individual responsible for managing the implementation to conclusion and will be the principal contact for the Participating Authority during implementation.

6.3.2. Identify all key decision makers involved in the implementation of the Contract at the Participating Authority.

6.3.3. The co-ordination of any sub-contracting arrangements required to fully service the Contract as specified.

6.3.4. Specific, achievable target dates for each stage of the implementation including a final date for the conclusion of the Contract Implementation Plan and the commencement of the Services. Where sub-contracting arrangements are required to fully service the Contract as specified, the co-ordination of these will be laid out in the Contract Implementation Plan.

6.4. The Implementation Plan provided by the Supplier is subject to alteration and agreement with the Participating Authority(s).

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

6.6. The Supplier will attend an initial engagement meeting with the Participating Authority.

6.7. The required frequency of operational, contractual and monitoring meetings between the Supplier and Participating Authority will be agreed at implementation stage.

6.8. The Supplier will achieve value for money and continuous improvement which will be measured by Key Performance Indicators agreed with the Participating Authority. Key Performance Indicators may include but not be restricted to:

6.8.1. Improved times to treatment

6.8.2. The percentage of reports delivered within the agreed timescales for each complexity and report type required

6.8.3. The number of reports requested each period

6.8.4. The number of reports audited each period, and the percentage that were compliant

7. Training

7.1. Where required, the Supplier must provide comprehensive training to employees of the Participating Authority on how to use all elements of the Services as relevant to the requirements of the Participating Authority. The training will be provided free of charge.

7.2. Training should be provided for all employees of the Participating Authority who require it.

7.3. Training may be in the following methods: face to face (group or individual), videoconference, tele-conference, email, and literature guidance.

7.4. Training will be planned and provided as part of the Contract Implementation Plan and must be provided prior to the commencement of the Services.

7.5. The Supplier will provide additional ad-hoc support and training throughout the Term of the Call-Off Contract as reasonably required by the Participating Authority. This will be undertaken within specified hours agreed with the Participating Authority at Contract Implementation.

7.6. The Supplier will provide additional training to new employees of the Participating Authority if required.

7.7. The Supplier will provide additional training as a result of a change or update to the Services if this is required.

7.8. Should training be required for an element of the services provided by a subcontractor, the Supplier must organise for this training to be carried out in accordance with the Training requirements within this Specification.

8. Transition

8.1. The Supplier will work closely with the Participating Authority to produce a detailed exit plan for the end of each Contract called off from the Framework Agreement.

8.2. In the event of the termination or expiry of the Contract, the Supplier will work co-operatively with the Participating Authority and/or the incoming Supplier to ensure smooth transition to the new Supplier.

8.3. The Supplier will provide a detailed exit plan during contract implementation for review and approval by the Participating Authority.

8.4. There will be no costs incurred by any Participating Authority with respect to the termination or expiry of the contract.

9. Service Management

9.1. The service will facilitate discussions with stakeholders and, wherever possible, engage in collaborative working for the benefit of patients.

9.2. The service will maximise the use of new innovations and technology where evidence-based.

9.3. Where optimal technologies are not currently available it is expected that the Supplier will move towards new ways of working during the lifetime of the Framework Agreement and any Contracts awarded under it.

9.4. The Supplier will ensure they have robust business continuity plans in place to ensure continued service is provided to patients in the advent of disruption, which could include loss of power, IT, staff sickness, strikes, adverse weather including snow, flood etc.

9.5. The Supplier shall maintain standard Business Hours as a minimum, which are a minimum of 8 hours between the hours of 8:00am and 6:00pm, Monday to Friday.

9.6. The Supplier will be expected to implement a set of policies relating to customer service, employee etiquette and Service availability. These will be agreed with the Participating Authority at Contract Implementation. The Supplier may be required upon request to produce evidence demonstrating that adherence to the policies has been monitored and recorded.

9.7. The Supplier must provide each Participating Authority with a named dedicated account manager who will be the single point of contact for the duration of the Contract.

10. Data Protection and Information Management

10.1. The Supplier(s) must comply with, and operate in accordance with, the most recent regulations regarding data sharing and transfer.

10.2. The Supplier must comply with the Data Protection Act 2018 and should demonstrate compliance with the General Data Protection Regulations (GDPR).

10.3. The Supplier must evidence an audit trail of personnel accessing patient identifiable data, as and when requested.

10.4. The Supplier must have a robust policy in place that details the management of patient data, information storage, disposal, and disaster recovery of data.

10.5. The Supplier must have the capability to provide reports via a secure network portal.

10.6. The portal must ensure the secure and protected transfer of patient data, reporting and communications between the systems of the Supplier and the Participating Authority. The portal must record fully, including user identification, all instances of personnel accessing patient identifiable data and sensitive information.

10.7. The Supplier must adhere to the IT policy, data management and security policies of each individual Participating Authority, the details of which will be agreed at Contract Implementation.

11. Clinical Governance

11.1. The Supplier must commit to comply with any Participating Authority's policies and procedures appropriate to the performance of the Services, including but not restricted to clinical governance policies and risk management strategies. These may

be developed between the Supplier and the Participating Authority to ensure that they are relevant to the service and appropriate for the service level being provided. Participating Authorities will provide relevant policies to the Supplier as necessary or upon written request.

11.2. The Supplier must have robust, clearly defined and auditable quality assurance processes to ensure that Services are carried out to the satisfaction of any Participating Authority that chooses to contract with the Supplier for the services covered by this Framework which will ensure:

11.2.1. Adherence to the Participating Authority's Policies and Procedures

11.2.2. All requirements relating to health and safety in the workplace are satisfied

11.2.3. Professionals are appropriately trained and competent to perform duties required of their role

11.3. The Supplier must have a robust, clearly defined and auditable information system security management system to protect Patient data.

11.4. The Supplier must operate within Care Quality Commission (CQC) System Guidelines and the guidelines outlined within the Participating Authority's own Standard Operating Procedures throughout the life of the Agreement and during any Contract whose performance concludes outside the period of the Framework Agreement.

11.5. The Supplier must be registered with the Care Quality Commission and must maintain this throughout the term of the Framework Agreement and any Contracts awarded underneath it.

11.6. The Supplier will implement specific audit arrangements and submit evaluation of audits to the Framework Manager or to any Participating Authority on request.

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

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

11.9. The Supplier must have a robust system in place for reporting patient safety incidents and reviewing of this data at appropriate levels.

11.10. The Supplier will investigate and manage Serious Untoward Incidents and complaints in line with the agreed complaints and incident reporting procedures, implementing the NHS Commissioning Board Special Health Authority (formerly NPSA) investigation toolkit (or the procedures of equivalent organisations in Scotland, Wales and Northern Ireland, where applicable).

12. **Corporate Governance**

12.1. The Supplier will be responsible for:

12.1.1. Delivering the services in the agreed service environment

12.1.2. Leadership of their clinical team

12.1.3. Provision of clinical guidance and support where necessary to ensure that their staff work to a clinical governance framework

12.1.4. Ensuring that all staff are competent to perform all duties that are required of their role

12.1.5. Access to relevant training and Continuous Professional Development (CPD) for clinical and non-clinical staff

12.1.6. Leading in audit, service evaluation and service development

12.2. The Supplier must have robust, auditable management and corporate governance procedures including clear responsibilities for all staff and appropriate employment policies and procedures, insurances and indemnities and, where relevant, clear written agreements with sub-contractors.

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

12.4. The Supplier must comply with the following:

12.4.1. Data Protection Act 2018

12.4.2. Caldicott Guidelines 1997

12.4.3. The relevant requirements of the Access to Health Records Act 1990

12.4.4. Access to Medical Reports Act 1988

12.4.5. Confidentiality Code of Practice 1998

12.4.6. The relevant requirements of the Care Standards Act 2000

12.4.7. Any other relevant statutory requirements.

12.4.8. Any amendments to the above.

12.5. The Supplier must be registered with the Information Commissioners Office as a Data Processer.

12.6. Patient records will remain the responsibility of the Participating Authority. The Supplier shall obtain no proprietary interest in any patient data and shall ensure the return of any material detailing or recording such patient data to the Participating Authority on demand.

12.7. The Supplier will ensure that all patients' case notes are kept securely and transferred to the Supplier securely where the Supplier needs such notes to perform its duties under the terms of the contracted service.

12.8. The Supplier shall ensure that all staff engaged to undertake any of the services fulfil all statutory requirements of employment including but not limited to the right to work in the UK.

12.9. The Supplier must ensure that all physicians are GMC registered and hold valid insurance obtained from MPS/MDDUS. The Supplier shall be responsible for ensuring compliance with all relevant HM Revenue and Customs regulations regarding the correct accounting for and payment of tax and National Insurance by and for staff engaged in the performance of the services.

12.10. The Supplier shall take all reasonable steps to ensure that no Participating Authority is exposed to any liabilities resulting from any part of the services being determined by HM Revenue and Customs as disguised employment as defined in 2017 Public Sector Contracting ("IR35") regulations.

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

12.12. Patients for whom reports are produced services will remain the overall responsibility of the Participating Authority and as such will be covered by each Participating Authority's NHS Resolution insurances. The Participating Authority will ensure that NHS Resolution is notified of the new sub-contract arrangements for the services. The Supplier must ensure that it retains all appropriate public liability, professional liability and employer liability insurance at all times throughout the life of the Agreement and during any treatments whose performance concludes outside the period of the Framework Agreement.

12.13. The Supplier shall produce to the Framework Manager or to any Participating Authority on request documentary evidence that the insurance required is properly maintained.

12.14. The Supplier will maintain a complaints procedure in line with applicable law and provide as and when necessary details of such a procedure to the Framework Manager or to any Participating Authority.

12.15. Where the Participating Authority wishes to make a complaint about the Supplier or an individual employee or any other element covered by the scope of the Services, the Supplier shall operate a clear and written procedure for handling such complaints.

12.16. The Supplier shall inform the Framework Manager of any complaints made by any Participating Authority and supply copies of all correspondence to the Framework Manager which relates to complaints or the handling of them.

12.17. In the event that complaints regarding the services are made by patients to a Participating Authority, the Participating Authority will forthwith inform the Supplier and supply relevant correspondence.

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

12.18.1. Appoint a complaints manager or individual with complaints remit

12.18.2. Provide the Framework Manager and any Participating Authority with relevant details of the complaints manager

12.19. The Supplier will undertake where requested to provide information to the Participating Authority to support the Participating Authority's adherence to national or local frameworks for performance reporting.

12.20. The Supplier will collect and provide anonymised data to the Participating Authority for assessment of Patient Reported Outcome Measures.

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

12.22. The Supplier must comply with all current and future Legislation and Regulations applicable to the transfer of data outside of the United Kingdom. The Supplier may be required to provide evidence, upon request, demonstrating compliance to these mandatory requirements through the lifetime of the Framework and any subsequent Call-Off Contracts with the Participating Authority.

12.23. If the Supplier deploys, in the provision of the Services, reporting members of staff located outside of the United Kingdom and doing so results in the international transfer of personal or sensitive data, this shall be subject to approval by the Framework Manager and the Participating Authority who require notification of this activity prior to the commencement of the Services.

12.24. The Supplier shall ensure that all staff engaged to undertake any of the services fulfil all statutory requirements of employment including but not limited to the right to work in the UK.

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

13. **Registration and Standards**

13.1. The Supplier must be registered with the Regulatory Body, Care Quality Commission (or equivalent Regulatory Body depending on the region of the Participating Authority) and shall be subject to its regulations and standards.

13.2. The Supplier must demonstrate compliance to the standards on image and report sharing and patient safety. This should include, but not be limited to;

13.2.1. Data Security and Protection Toolkit Statement of Compliance

13.2.2. service delivery through a secure network portal

13.2.3. European Working Time Directive

13.3. The Supplier must hold and maintain Cyber Security Essentials Plus accreditation throughout the period of the Framework Agreement and any Contract called off from the Framework Agreement.

LOT 3 – RADIOLOGY WORKFLOW MANAGEMENT SYSTEMS

1. Radiology Workflow Management Systems

1.1. Radiology Workflow Management Systems are defined as the software and hardware which enable a radiology department to access real time data to improve productivity and efficiency.

1.2. A Radiology Workflow Management System is expected to provide:

1.2.1. Technology to accurately forecast reporting capacity, enabling optimisation of departmental rotas and strategic recruitment based on supply and demand mismatches.

1.2.2. Highly secure data capture, transmission, storage and analysis.

1.2.3. Easy to read dashboards which reflect all the data captured. Dashboards should be customisable to each speciality or management professional.

1.2.4. Easy to read reports in commonly used formats.

1.3. Systems should be user friendly and intuitive to use.

1.4. Systems will be customisable to meet the requirements set out in this specification and the requirement of Contracting Authorities.

2. General Requirements

2.1. Systems must not compromise any Contracting Authority's compliance with the NHS Data Security and Protection Toolkit (DSPT) Standard.

2.2. Systems must support role-based user access and be accessed through secure password or pass card.

2.3. Systems should ideally provide that screens lock after a predefined period of inactivity if required and log a user out of the system on screen lock.

2.4. Users must log in to the system to access any functionality.

2.5. Systems must support the authentication of individual users and not just groups.

2.6. All user authorisation facilities must be maintained centrally and integrated across all system modules, such that user/group access profiles can be defined once and applied consistently through the system.

2.7. Systems must be capable of implementing and supporting role-based access and allow different user profiles to be linked to a user's Active Directory profile.

2.8. Systems must contain controls that can ensure that individuals can be held accountable for their actions.

2.9. Systems must be compatible with all commonly used server/client anti-virus software.

2.10. The transfer of data via wireless or fixed line communications must be protected from interception, where sensitive data is being transmitted over a public network, e.g., the internet.

2.11. Data transferred and/or stored must be encrypted, with an encryption key length of 128 bits as a minimum with wireless keys.

2.12. Backup processes must not involve system down time, interruption or degradation of service.

2.13. Systems must be available to staff 24 hours per day, 7 days per week and 365 days per year (366 days in a leap year). Any system must provide for a complete disaster recovery (DR), which will require the same level of support as the normal live system.

2.14. Systems, if web-enabled, must operate properly with standard configurations of all commonly available network browsers. Any restrictions on network browsers or on versions thereof supported must be notified to the Framework Manager and to Contracting Authorities.

2.15. Systems must conform to W3C DFA (Designed for all) Standards.

2.16. Suppliers must operate a defined quality management system for the design, development, manufacture, service, installation and distribution of their Radiology Workflow Management Systems to the standard of EN ISO 9001:2008 or operate a quality management system to an equivalent level. Details of this quality management system will be made available to Contracting Authorities on request.

2.17. Suppliers must follow a defined and documented software quality accreditation process to a level at least equivalent to that of IS EN ISO 9001:2008 (or an equivalent recognised standard).

2.18. Suppliers must operate a defined and documented information system security management system to a level at least equivalent to that of IS EN ISO 27001:2013 (or an equivalent recognised standard). Details of this information system security management system will be made available to Contracting Authorities on request.

2.19. Suppliers must hold (or commit to obtain, prior to commencement of the Framework Agreement if awarded) Cyber Security Essentials Plus accreditation.

2.20. Suppliers should be committed to continuous product improvement with a clear development roadmap for their product/applications proposed.

2.21. Suppliers must be registered with the Information Commissioners Office as a Data Processer throughout the life of the Framework Agreement and the period of all Contracts called off from the Framework Agreement.

2.22. Suppliers must take full responsibility for implementing and supporting their Radiology Workflow Management System regardless of whether those goods or services are delivered by the vendor or a third party(s).

2.23. Suppliers must hold, and commit to hold throughout the period of the Framework Agreement and any Contracts called off from the Framework Agreement, all necessary OEM accreditations and licences and rights to exploit any intellectual property for each element of software modules that are considered to form part of the product/application proposed.

3. Reporting Analysis and Audit

3.1. Systems will provide a live operational view of the entire radiology department across a single hospital and across a healthcare group of organisations.

3.2. Systems must have the ability to provide aggregate reports at healthcare group level and at single/multiple hospital level.

3.3. Systems will have the ability to accurately forecast reporting capacity for a department on a daily, weekly, monthly and annual basis.

3.4. Systems will highlight mismatches between capacity and demand to allow optimisation of departmental rotas.

3.5. Systems will highlight long-term gaps in general staffing, reporting sub-specialties and modalities to allow for targeted recruitment.

3.6. Systems will have the ability to output to printers, screens, multi-function devices and files.

3.7. Systems must have a detailed audit trail capability.

3.8. Systems will have the capability and functionality to conduct user/hospital/group/national audits.

4. Support

4.1. Suppliers will provide support for both functional and non-functional components of their system. Support will be available for the following areas at a minimum:

4.1.1. Support at Go-Live

4.1.2. Post Go-Live support (including out of hours support)

4.1.3. Call logging procedures and response times

4.1.4. Escalation procedures

4.1.5. Business Continuity and Recovery

4.1.6. New Functionality / Requirements Requests

5. Training

5.1. Suppliers will provide comprehensive training, both on-site and on-line, to support the successful implementation of their system.

5.2. Training for key staff will be available during implementation, at go live and in the post go live period.

5.3. Training will be tailored to the needs of potential users across the hospital and or healthcare system.

5.4. Suppliers will provide Contracting Authorities with online documentation to assist the Contracting Authority in its use of the Radiology Workflow Management System.