APPENDIX 3

FRAMEWORK AGREEMENT SPECIFICATION
IMAGING, RADIOTHERAPY AND ENDOSCOPY EQUIPMENT, ANCILLARY DEVICES AND ASSOCIATED GOODS AND SERVICES

1. Introduction

1.1. The Framework Agreement is for supply of Medical Imaging and Radiotherapy equipment including the associated products and services required in their use.

1.2. By submitting a product as part of the tender process the Applicant is confirming that the product meets all requirements of this Specification (including any applicable Lot specific Specifications hereafter). Any products which are submitted for inclusion as part of a range extension request during the term of the Framework Agreement must also comply with the requirements of this specification (including any applicable Lot specific Specifications).

1.3. Alongside this specification document Applicants must also meet the requirements outlined in the relevant Lot specific Specifications.

1.4. The Framework Agreement is for the following Lots:

Lot Number	Lot Title	Lot specific Specification
1	CT scanners and associated options and related services	Appendix 3a
2	MRI scanners and associated options and related services	Appendix 3b
3	Nuclear medicine imaging and associated options and related services	Appendix 3c
4	Fluoroscopy and associated options and related services	Appendix 3d
5	Mobile image intensifiers and associated options and related services	Appendix 3e
6	Mobile X-Ray systems and associated options and related services	Appendix 3f
7	Static X-Ray systems and associated options and related services	Appendix 3g
8	Contrast injectors, consumables and associated options	Appendix 3h
9	Lithotripsy and associated options and related services	Appendix 3i
10	DEXA scanners and associated options and related services	Appendix 3j
11	Ultrasound scanners and associated options and related services	Appendix 3k
12	Mammography imaging systems and associated options and related services	Appendix 3l
13	Specimen cabinets and associated options and related services	Appendix 3m
14	Bladder scanners and associated options and related services	Appendix 3n

15	Radiotherapy treatment systems and associated options and related services	Appendix 3o
16	Radiotherapy IT solutions and associated options and related services	Appendix 3p
17	Radiotherapy ancillary devices including dosimetry, patient positioning and quality assurance devices	Appendix 3q
18	Brachytherapy seeds and associated accessories	Appendix 3r
19	Surgical navigation systems, accessories and associated options and related services	Appendix 3s
20	Flexible endoscopes and associated options and related services	Appendix 3t
21	Ear, nose and throat (ENT) endoscopes and associated options and related services	Appendix 3u
22	Rigid endoscopes and associated options and related services	Appendix 3v

1.5. Full technical specifications of the product lines awarded to the Framework Agreement (each a "**Technical Specification**" and together the "**Technical Specifications**") must be made available to NHS Supply Chain on request during the term of the Framework Agreement.

1.5.1. Applicants must notify NHS Supply Chain immediately about any proposed changes to the Technical Specifications throughout the term of the Framework Agreement.

1.5.2. 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.

1.5.3. NHS Supply Chain reserves the right to request evidence of compliance with the Specification throughout the term of the Framework Agreement. NHS Supply Chain reserves the right to exclude and/or suspend awarded product lines from the Framework Agreement which do not meet the minimum Specification requirements.

1.6. For the purposes of the financial evaluation of this tender, core imaging radiotherapy, endoscopy, and ancillary devices product lines have been specified for each Lot and are detailed within Appendices 3a – 3v Lot specifications.

1.7. NHS Supply Chain reserve the right to review specifications during the term of the Framework Agreement.

2. Standards, Regulations and Legislation

2.1. This Framework Agreement Specification makes reference to a number of standards and legislation. The list of standards and legislation is not intended to be exhaustive and any relevant standards and legislation which applies to the Framework Agreement (even if not stated, and including any introduced

throughout the lifetime of this Framework Agreement) must be complied with by Applicants (together with those listed in this Framework Agreement Specification the "**Standards and Legislation**").

2.2. Product lines must comply with the Standards and Legislation (as amended, extended or re-enacted from time to time).

STANDARD AND LEGISLATION
All products must be CE Marked to the appropriate Directive / Regulation, including: **Medical Devices Directive 93/42/EEC (as amended)** All products must have their CE marking evident on the product and/or packaging. **Medical Devices Regulation 2017/745** (as amended) All products must have their CE marking evident on the product and/or packaging. **UKCA Mark** All products must have the UKCA marking evident on the product and/or packaging. **NHS Supply Chain understands that some requirements detailed above, such as the Medical Devices Regulation 2017/745, have a deadline to achieve accreditation in the future. Applicants confirm, by signing Appendix 2 Form of Offer (and if awarded the Framework Agreement), that they will achieve the relevant accreditation by the deadline. If awarded to the Framework Agreement, it will be the responsibility of the Applicant to ensure compliance with such requirements.**

2.3. Electrical product lines must comply with the requirements of the Directive on waste electrical and electronic equipment (WEEE Directive 2012/19/EU) and the Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS 2 Directive 2011/65/EU).

2.4. During the term of the Framework Agreement Applicants must make NHS Supply Chain aware of any awarded product line that is classed by the MHRA as a Medicinal Product.

3. Health and Safety

3.1. Applicants must provide NHS Supply Chain with Safety Data Sheets (SDS) for all products that fall under REACH (Registration, Evaluation, Authorisation and restriction of Chemicals) 2007 –more specifically, an SDS must be provided if a

substance or a mixture supplied is classified as hazardous under the CLP Regulation (EC) No 1272/2008.

3.2. If a product line contains phthalates this must be indicated on the packaging of that product line in accordance with Directive 2007/47/EC (amending Directives 90/385/EEC and 93/42/EEC).

3.3. All product lines and packaging should be latex free where possible. If a product line or any packaging **contains** or **does not contain** latex this must be labelled on the product line or packaging (as applicable) to inform the user.

3.4. All patient contact areas must be sealed to minimise the ingress of bodily fluids and the whole system must be easy to wipe clean with proprietary detergents and/or alcohol wipes.

4. Delivery and Installation

4.1. All product lines must be delivered free of charge to a location as directed by either NHS Supply Chain or the customer.

4.2. Installation is required (excluding any interface not specified in the equipment specification) and must be free of charge and undertaken at a location within the UK as specified by the customer.

4.3. Where applicable, products must be compatible with the UK electrical distribution system.

5. Training and Warranty

5.1. Where a warranty is provided it must be free of charge warranty for a minimum of 12 months (including repair, parts, labour and servicing) from the date of acceptance by the customer.

5.2. Initial end user training must be provided free of charge at a time requested by the customer within 24 months of installation.

5.3. All equipment must be supplied with a user instruction guide / operator manual in English either on CD, online or as a printed copy.

6. IT and Software

6.1. Software for all equipment must be supplied in accordance with Schedule 7 of Appendix 4a – Call off Terms and Conditions.

6.2. All embedded software and operating systems must be included in the system configuration and tendered price.

6.3. System operating updates must not compromise the safety of patients. There must be the ability to revert to a previous version of software should the user experience any issues with the system operation as a result of the update.

6.4. All awarded product lines must have an audit trail of software patches and installations which must be available to access by the customer.

6.5. Where applicable awarded product lines must incorporate cyber security to protect against malicious software. This must be included in the system configuration and the tendered price.

6.6. Any remote access of awarded product lines for monitoring, repair or other reason must be done securely and ensure data protection.

6.7. All awarded product lines, where applicable, must have the functionality to apply administration rights, reset passwords, retrieve forgotten passwords, set up user authorisations, and log user interactions.

6.8. Where applicable, products must support relevant **NEMA PS3/ISO 12052, Digital Imaging and Communications in Medicine (DICOM) standard, National Electrical Manufacturers Association, Rosslyn, VA, USA (available free at http://medical.nema.org/)** service classes hereafter referenced as DICOM.

6.8.1. The DICOM conformance statement must be supplied.

6.8.2. Any DICOM conformance claimed therein is assumed supplied and enabled.

6.8.3. Specific service class requirements are outlined in the individual Lot specifications.

6.9. Where applicable all Applicants must meet the DSP Toolkit Standards as set out by NHS Digital for more information please see https://www.dsptoolkit.nhs.uk/Help/overview.