National Framework Agreement for Non-Wire Lesion Localisation & Sentinel Lymph Node Location Products

Project Reference: F/062/LOC/19/IB

FRAMEWORK AGREEMENT SPECIFICATION

LOT 1a

SUPPLY OF NON-WIRE LESION LOCALISATION DETECTORS

1. Specification requirements

1.1 Suppliers appointed to Lot 1a of the Framework agreement will meet the following requirements.

1.1.1 The Supplier will supply products to NHS Organisations that enable accurate location of and guidance to non-palpable lesions without use of a localisation guide wire.

1.1.2 The Supplier will supply non-wire lesion localisation products that have an excellent level of safety.

1.1.3 The Supplier will supply non-wire lesion localisation products that have an excellent level of accuracy and effectiveness.

1.1.4 Detectors supplied under the framework agreement will be capable of locating and indicating the position of an implanted lesion localisation implant with a consistently high level of accuracy.

1.1.5 Detectors supplied under the framework agreement will be simple to operate and read by suitably trained and qualified NHS staff.

1.1.6 In the event that one or more of the Supplier's non-wire lesion localisation detectors is withdrawn from sale and contraindicated for further use by NHS Organisations due to product safety concerns, the Supplier will replace each item purchased by NHS Organisations with non-wire lesion localisation detectors of equivalent functionality at no charge to the NHS Organisation. If different non-wire lesion localisation implants & associated implantation devices are required for any replacement non-wire lesion localisation detectors provided to NHS Organisations in line with provisions of this clause 1.1.6, and the Supplier is appointed to Lot 1b of the framework agreement these non-wire lesion localisation implants & associated implantation devices will be supplied at the same price as the equivalent non-wire lesion localisation implants & associated implantation devices previously supplied. For the avoidance of doubt, this clause will not apply where product safety concerns have arisen directly as the result of the actions or inactions of the NHS Organisation. This clause will apply where product safety concerns have arisen directly as the result of the actions or inactions of the Supplier.

1.1.7 Where the Supplier offers both detectors and compatible non-wire lesion localisation implants & associated implantation devices under the framework agreement, and the Supplier is appointed to both Lot 1a and Lot 1b of the framework agreement the Supplier will supply the range of reusable and single-use, non-wire lesion localisation implants & associated implantation devices described in Lot 1b that is fully compatible with any non-wire lesion localisation detector that is withdrawn from sale for a period of seven (7) years after the withdrawal from sale date. For the avoidance of doubt, this provision will not apply to non-wire lesion localisation products that are withdrawn from sale and contraindicated for further use by NHS Organisations due to product safety concerns.

1.1.8 Non-wire lesion localisation detectors supplied under the framework agreement will be highly reliable and consistent in performance. Equipment uptime percentage and mean time between failures should be high.

1.1.9 Where required, the Supplier will offer comprehensive training in the use of their non-wire lesion localisation detectors to appropriate clinical staff of NHS Organisations.

1.1.10 The Supplier will provide instructions for NHS Organisations on the safe, efficient and effective decontamination of the Supplier's non-wire lesion localisation detectors.

1.1.11 Where required, the Supplier will provide all certification, documentation and support necessary for an NHS Organisation's Medical Engineering, Electronics & Bio-Medical Engineering (EBME) or provider of such services to conduct such engineering safety checks on the Supplier's non-wire lesion localisation detectors that are required by the NHS Organisation.

1.1.12 The Supplier will provide a comprehensive warranty of at least 12 months duration from the date of delivery or acceptance, whichever is later, covering the Supplier's non-wire lesion localisation detectors that will include any consumables and parts.

1.1.13 The Supplier will provide maintenance, inspections and software update services to ensure optimal equipment performance and minimise equipment downtime. Software updates will be included at no additional cost in all levels of maintenance plan.

1.1.14 The Supplier will provide maintenance, inspections and software update services for any of the Supplier's non-wire lesion localisation detectors that are withdrawn from sale for a period of seven (7) years after the withdrawal from sale date. For the avoidance of doubt, this provision will not apply to non-wire lesion localisation detectors that are withdrawn from sale and contraindicated for further use by NHS Organisations due to product safety concerns.

1.1.15 The Supplier will provide a detailed maintenance schedule to each NHS Organisation purchasing the Supplier's non-wire lesion localisation detectors.

1.1.16 The Supplier will provide an experienced, multi-person UK based service organisation available for maintenance and support.

1.1.17 The Supplier will provide guaranteed minimum response times for the attendance of a service engineer on site if required by an NHS Organisation.

1.1.18 The Supplier will provide loan equipment to NHS Organisations during planned or unplanned equipment downtime.

1.1.19 Where required, the Supplier will provide training and supply parts to an NHS Organisation's Medical Engineering, Electronics & Bio-Medical Engineering (EBME) or provider of such services to allow first-line maintenance of the Supplier's non-wire lesion localisation detectors, where possible and appropriate.

1.1.20 The Supplier will provide technical support services to enable the most efficient and effective use of the Supplier's non-wire lesion localisation detectors.

1.1.21 The Supplier will have short lead times for the delivery of non-wire lesion localisation detectors. The Supplier's On Time In Full (OTIF) percentage for delivery should be high and may be included as a Key Performance Indicator by an NHS Organisation for their Call Off Contract.

1.1.22 Where required, the Supplier will have short lead times for the delivery of parts to an NHS Organisation's Medical Engineering, Electronics & Bio-Medical Engineering (EBME) or provider of such services to allow first-line maintenance of the non-wire lesion localisation detectors, where applicable. The Supplier's On Time In Full (OTIF) percentage for parts delivery, where applicable, should be high and may be included as a Key Performance Indicator by an NHS Organisation for their Call Off Contract.

2. Standards

2.1 All products supplied under the Framework Agreement must be CE certified under the relevant directive.

2.2 The Supplier must operate a defined and documented quality management system for the design, development, manufacture, service and distribution of its products to a level at least equivalent to that required to achieve ISO 13485:2016 or ISO 9001:2015 (or an equivalent recognised standard) certification. Details of this quality management system will be made available to NHS Organisations on request.

2.3 The Supplier must operate a defined quality management system for its training, servicing and technical support services. Details of this quality management system will be made available to NHS Organisations on request.

LOT 1b

SUPPLY OF NON-WIRE LESION LOCALISATION IMPLANTS & ASSOCIATED IMPLANTATION DEVICES

1. Specification requirements

1.1 Suppliers appointed to Lot 1b of the Framework agreement will meet the following requirements.

1.1.1 The Supplier will supply products to NHS Organisations that enable accurate location of and guidance to non-palpable lesions without use of a localisation guide wire.

1.1.2 The Supplier will supply non-wire lesion localisation implants & associated implantation devices that have an excellent level of safety.

1.1.3 Non-wire lesion localisation implants supplied under the framework agreement will be simple to place and easy to remove using the associated implantation devices when used by suitably trained and qualified NHS staff.

1.1.4 Non-wire lesion localisation implants supplied under the framework agreement will be easy to detect pre-incision and intra-operatively using X-ray or other means of detection commonly used by NHS Organisations.

1.1.5 In the event that one or more of the Supplier's non-wire lesion localisation implants & associated implantation devices is withdrawn from sale and contraindicated for further use by NHS Organisations due to product safety concerns, the Supplier will replace each item purchased by NHS Organisations with non-wire lesion localisation implants & associated implantation devices of equivalent functionality at no charge to the NHS Organisation. If different non-wire lesion localisation detectors are required for any replacement non-wire lesion localisation implants & associated implantation devices provided to NHS Organisations in line with provisions of this clause 1.1.5, and the Supplier is appointed to Lot 1a of the framework agreement these non-wire lesion localisation detectors will be supplied at the same price as the equivalent non-wire lesion localisation detectors previously supplied. For the avoidance of doubt, this clause will not apply where product safety concerns have arisen directly as the result of the actions or inactions of the NHS Organisation. This clause will apply where product safety concerns have arisen directly as the result of the actions or inactions of the Supplier.

1.1.6 Reusable and single-use implants & associated implantation devices supplied under the framework agreement including but not limited to seeds and seed insertion devices will be compatible with non-wire lesion localisation detector(s) that are readily available to NHS Organisations.

1.1.7 Non-wire lesion localisation implants & associated implantation devices supplied under the framework agreement will be highly reliable and consistent in performance.

1.1.8 Where required, the Supplier will offer comprehensive training in the use of their non-wire lesion localisation implants & associated implantation devices to appropriate clinical staff of NHS Organisations.

1.1.9 All of the Supplier's non-wire lesion localisation implants will have a long shelf life and suffer no loss of effectiveness after prolonged storage.

1.1.10 If applicable, the Supplier will provide information to NHS Organisations on the proper storage, handling, use, and disposal of any radioactive implants, such as Iodine^{125} seeds, supplied by the Supplier.

1.1.11 If applicable, the Supplier will offer a disposal service of any of the Supplier's radioactive implants that supports an NHS Organisation's Administration of Radioactive Substances Advisory Committee (ARSAC) licence for the administration of radioactive substances for the purposes of diagnosis, therapy and research.

1.1.12 The Supplier will provide instructions for NHS Organisations on the safe, efficient and effective decontamination of any of the Supplier's reusable non-wire lesion localisation implantation devices.

1.1.13 Where required, the Supplier will provide all certification, documentation and support necessary for an NHS Organisation's Medical Engineering,

Electronics & Bio-Medical Engineering (EBME) or provider of such services to conduct such engineering safety checks on any of the Supplier's reusable non-wire lesion localisation implantation devices that are required by the NHS Organisation.

1.1.14 The Supplier will provide a comprehensive warranty of at least 12 months duration from the date of delivery or acceptance, whichever is later, covering all of the Supplier's reusable non-wire lesion localisation implantation devices.

1.1.15 The Supplier will provide a detailed maintenance schedule to each NHS Organisation purchasing the Supplier's reusable non-wire lesion localisation implantation devices.

1.1.16 The Supplier will provide an experienced, multi-person UK based service organisation available for maintenance and support.

1.1.17 The Supplier will provide guaranteed minimum response times for the attendance of a service engineer on site if required by an NHS Organisation.

1.1.18 The Supplier will provide loan equipment to NHS Organisations during planned or unplanned equipment downtime.

1.1.19 Where required, the Supplier will provide training and supply parts to an NHS Organisation's Medical Engineering, Electronics & Bio-Medical Engineering (EBME) or provider of such services to allow first-line maintenance of the Supplier's reusable non-wire lesion localisation implantation devices, where possible and appropriate.

1.1.20 The Supplier will provide technical support services to enable the most efficient and effective use of the Supplier's non-wire lesion localisation implants & associated implantation devices.

1.1.21 The Supplier will have short lead times for the delivery of non-wire lesion localisation implants & associated implantation devices. The Supplier's On Time In Full (OTIF) percentage for delivery should be high and may be included as a Key Performance Indicator by an NHS Organisation for their Call Off Contract.

1.1.22 Where required, the Supplier will have short lead times for the delivery of parts to an NHS Organisation's Medical Engineering, Electronics & Bio-Medical Engineering (EBME) or provider of such services to allow first-line maintenance of the Supplier's reusable non-wire lesion localisation implantation devices, where applicable. The Supplier's On Time In Full (OTIF) percentage for parts delivery, where applicable, should be high and may be included as a Key Performance Indicator by an NHS Organisation for their Call Off Contract.

2. Standards

2.1 All products supplied under the Framework Agreement must be CE certified under the relevant directive.

2.2 The Supplier must operate a defined and documented quality management system for the design, development, manufacture, service and distribution of its products to a level at least equivalent to that required to achieve ISO 13485:2016 or ISO 9001:2015 (or an equivalent recognised standard) certification. Details of this quality management system will be made available to NHS Organisations on request.

2.3 The Supplier must operate a defined quality management system for its training, servicing and technical support services. Details of this quality management system will be made available to NHS Organisations on request.

LOT 2a

SUPPLY OF SENTINEL LYMPH NODE LOCATION DETECTORS

1. Specification requirements

1.1 Suppliers appointed to Lot 2a of the Framework agreement will meet the following requirements.

1.1.1 The Supplier will supply products to NHS Organisations that enable accurate location of sentinel lymph nodes.

1.1.2 The Supplier will supply a sentinel lymph node location detector or detectors with an excellent level of safety.

1.1.3 The Supplier will supply sentinel lymph node location detector or detectors with an excellent level of accuracy and effectiveness.

1.1.4 The Supplier will supply a sentinel lymph node location detector or detectors that is/are capable of locating sentinel lymph nodes in patients (who have been previously injected with tracer fluid) with a consistently high level of accuracy.

1.1.5 The Supplier will supply a sentinel lymph node location detector or detectors that is/are simple to operate and read by suitably trained and qualified NHS staff.

1.1.6 In the event that one or more of the Supplier's sentinel lymph node location detectors is withdrawn from sale and contraindicated for further use by NHS Organisations due to product safety concerns, the Supplier will replace each item purchased by NHS Organisations with sentinel lymph node location detectors of equivalent functionality at no charge to the NHS Organisation. If different tracer fluid is required for any replacement sentinel lymph node location detectors provided to NHS Organisations in line with provisions of this clause 1.1.6, and the Supplier is appointed to Lot 2b of the framework agreement this tracer fluid will be supplied at the same price as the equivalent tracer fluid previously supplied. For the avoidance of doubt, this clause will not apply where product safety concerns have arisen directly as the result of the actions or inactions of the NHS Organisation. This clause will apply where product safety concerns have arisen directly as the result of the actions or inactions of the Supplier.

1.1.7 Where the Supplier offers both detectors and compatible consumables under the framework agreement, and the Supplier is appointed to both Lot 2a and

Lot 2b of the framework agreement the Supplier will supply the range of reusable and single-use, consumables described in Lot 1b that is fully compatible with any sentinel lymph node location detector that is withdrawn from sale for a period of seven (7) years after the withdrawal from sale date. For the avoidance of doubt, this provision will not apply to sentinel lymph node location products that are withdrawn from sale and contraindicated for further use by NHS Organisations due to product safety concerns.

1.1.8 The Supplier will supply sentinel lymph node location detectors that are highly reliable and consistent in performance. Equipment uptime percentage and mean time between failures should be high.

1.1.9 The Supplier will provide comprehensive training in the use of their sentinel lymph node location detector(s) to appropriate clinical staff of NHS Organisations.

1.1.10 The Supplier will provide instructions for NHS Organisations on the safe, efficient and effective decontamination of the Supplier's sentinel lymph node location detectors.

1.1.11 The Supplier will supply all certification, documentation and support necessary for an NHS Organisation's Medical Engineering, Electronics & Bio-Medical Engineering (EBME) or provider of such services to conduct such engineering safety checks on the Supplier's sentinel lymph node location detectors that are required by the NHS Organisation.

1.1.12 The Supplier will provide a comprehensive warranty of at least 12 months duration from the date of delivery or acceptance, whichever is later, covering all sentinel lymph node location detectors and parts.

1.1.13 The Supplier will provide maintenance, inspections and software update services to ensure optimal equipment performance and minimise equipment downtime. Software updates will be included at no additional cost in all levels of maintenance plan.

1.1.14 The Supplier will provide maintenance, inspections and software update services for any sentinel lymph node location detector that is withdrawn from sale for a period of seven (7) years after the withdrawal from sale date. For the avoidance of doubt, this provision will not apply to sentinel lymph node location detectors that are withdrawn from sale and contraindicated for further use by NHS Organisations due to product safety concerns.

1.1.15 The Supplier will provide a detailed maintenance schedule to each NHS Organisation purchasing the Supplier's sentinel lymph node location detectors.

1.1.16 The Supplier will provide an experienced, multi-person UK based service organisation available for maintenance and support.

1.1.17 The Supplier will provide guaranteed minimum response times for the attendance of a service engineer on site if required by an NHS Organisation.

1.1.18 The Supplier will provide loan equipment to NHS Organisations during planned or unplanned equipment downtime.

1.1.19 The Supplier will provide training and supply parts to an NHS Organisation's Medical Engineering, Electronics & Bio-Medical Engineering (EBME) or provider of such services to allow first-line maintenance of the sentinel lymph node location detectors, where possible and appropriate.

1.1.20 The Supplier will provide technical support services to enable the most efficient and effective use of the Supplier's sentinel lymph node location detectors.

1.1.21 The Supplier will have short lead times for the delivery of sentinel lymph node location detectors. The Supplier's On Time In Full (OTIF) percentage for delivery should be high and may be included as a Key Performance Indicator by an NHS Organisation for their Call Off Contract.

1.1.22 The Supplier will have short lead times for the delivery of parts to an NHS Organisation's Medical Engineering, Electronics & Bio-Medical Engineering (EBME) or provider of such services to allow first-line maintenance of the sentinel lymph node location detectors, where applicable. The Supplier's On Time In Full (OTIF) percentage for parts delivery, where applicable, should be high and may be included as a Key Performance Indicator by an NHS Organisation for their Call Off Contract.

2. Standards

2.1 All products supplied under the Framework Agreement must be CE certified under the relevant directive.

2.2 The Supplier must operate a defined and documented quality management system for the design, development, manufacture, service and distribution of its products to a level at least equivalent to that required to achieve ISO 13485:2016 or ISO 9001:2015 (or an equivalent recognised standard) certification. Details of this quality management system will be made available to NHS Organisations on request.

2.3 The Supplier must operate a defined quality management system for its training, servicing and technical support services. Details of this quality management system will be made available to NHS Organisations on request.

LOT 2b

SUPPLY OF SENTINEL LYMPH NODE LOCATION TRACER FLUID, EXCEPT RADIOISOTOPES

1. Specification requirements

1.1 Suppliers appointed to Lot 2b of the Framework agreement will meet the following requirements

1.1.1 The Supplier will supply products to NHS Organisations that enable accurate location of sentinel lymph nodes.

1.1.2 The Supplier will supply non-radioisotope sentinel lymph node location tracer fluid that is suitable for injection into interstitial tissue. Supply of radioisotopes for sentinel lymph node location is outside the scope of this Lot of this framework agreement.

1.1.3 Sentinel lymph node location tracer fluid supplied under the framework agreement will be compatible with a sentinel lymph node location detector or detectors that are readily available to NHS Organisations.

1.1.4 The Supplier will supply sentinel lymph node location tracer fluid with an excellent level of safety and patient tolerance.

1.1.5 The Supplier will supply sentinel lymph node location tracer fluid with an excellent level of effectiveness.

1.1.6 The Supplier's sentinel lymph node location tracer fluid(s) will have a long shelf life and suffer no loss of effectiveness after prolonged storage.

1.1.7 In the event that one or more of the Supplier's sentinel lymph node location tracer fluids is withdrawn from sale and contraindicated for further use by NHS Organisations due to product safety concerns, the Supplier will replace each item purchased by NHS Organisations with sentinel lymph node location tracer fluids of equivalent functionality at no charge to the NHS Organisation. If different sentinel lymph node location detectors are required for any replacement sentinel lymph node location tracer fluid provided to NHS Organisations in line with provisions of this clause 1.1.7, and the Supplier is appointed to Lot 2a of the framework agreement these sentinel lymph node location detectors will be supplied at the same price as the equivalent sentinel lymph node location detectors previously supplied. For the avoidance of doubt, this clause will not apply where product safety concerns have arisen directly as the result of the actions or inactions of the NHS Organisation. This clause will apply where product safety concerns have arisen directly as the result of the actions or inactions of the Supplier.

1.1.8 If applicable, the Supplier will provide information to NHS Organisations on the proper handling, use, and disposal of sentinel lymph node location tracer fluid(s) supplied by the Supplier, including information required under Control of Substances Hazardous to Health (COSSH) Regulations 2002 (and as amended).

1.1.9 The Supplier will provide technical support services to enable the most efficient and effective use of the Supplier's sentinel lymph node location tracer fluids.

1.1.10 The Supplier will have short lead times for the delivery of sentinel lymph node location tracer fluids. The Supplier's On Time In Full (OTIF) percentage for delivery should be high and may be included as a Key Performance Indicator by an NHS Organisation for their Call Off Contract.

2. Standards

2.1 All products supplied under the Framework Agreement must be CE certified under the relevant directive.

2.2 The Supplier must operate a defined and documented quality management system for the design, development, manufacture, service and distribution of its products to a level at least equivalent to that required to achieve ISO 13485:2016 or ISO 9001:2015 (or an equivalent recognised standard) certification. Details of this quality management system will be made available to NHS Organisations on request.

2.3 The Supplier must operate a defined quality management system for its training, servicing and technical support services. Details of this quality management system will be made available to NHS Organisations on request.