APPENDIX 3

FRAMEWORK AGREEMENT SPECIFICATION
NEONATAL EQUIPMENT, ADULT, PAEDIATRIC & NEONATAL PHOTOTHERAPY DEVICES

1. Introduction

1.1. The Framework Agreement is for the supply of neonatal equipment, adult, paediatric & neonatal phototherapy devices including: closed incubators; open warmer incubators; combined incubators, warmer with resuscitation incubator units; transport incubators; neonatal deceased cooling systems; jaundice meters; phototherapy devices (adult/paediatric & neonatal) and all related accessories. Related products within this framework include: cables, trolleys, software and any option or accessory used to configure a device within the Framework.

1.2. The Framework Agreement is for the following Lots

Lot Number	Lot Title
1	Neonatal Equipment and Associated Accessories
2	Phototherapy Devices (Adult & Paediatric) and Associated Accessories
3	Neonatal Deceased Cooling System and Associated Accessories

1.3. 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.

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

1.3.2. 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.

1.3.3. NHS Supply Chain reserves the right to request evidence of compliance with the Specification throughout the term of the Framework Agreement.

1.4. 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) must be complied with by Applicants

(together with those listed in this Framework Agreement Specification the "**Standards and Legislation**").

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

1.6. Evidence of compliance to the Standards and Legislation must be provided by Applicants awarded to the Framework Agreement ("**Suppliers**") to NHS Supply Chain on request during the term of the Framework Agreement; in the event that sufficient evidence is not provided by Suppliers NHS Supply Chain reserves the right to suspend product lines until such evidence is provided by Suppliers.

2. Criteria applicable across all lots:

2.1. Standards and Legislation

STANDARD AND LEGISLATION
Where products are classed as Medical Devices as per the definition under Medical Devices Regulation 2017/745 the following will apply: **Medical Devices Directive 93/42/EEC (as amended)** All products must have their CE or UKCA marking evident on the product and/or packaging. Or **Medical Devices Regulation 2017/745** (as amended) All products must have their CE marking evident on the product and/or packaging. **Non-Automatic Weighing Instruments Directive 2009/23/EC**

2.2. On request 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.

2.3. 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).

2.4. 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).

2.5. 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.

2.6. 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.

2.7. All product lines must be delivered free of charge to a location as directed by either NHS Supply Chain or the customer and must include a free of charge warranty for a minimum of 12 months (including repair, parts, labour and servicing) from the date of acceptance by the customer.

3. Lot 1 – Neonatal Equipment and Associated Accessories

3.1. An incubator is to provide a safe, controlled space whilst the Neonate develops, a multitude of treatments can then be provided. Jaundice Meters and Phototherapy devices are used to measure and treat high levels of Bilirubin. Products within this lot include:

- 3.1.1. Closed incubators;
- 3.1.2. Radiant warmers with beds;
- 3.1.3. Radiant warmers without beds;
- 3.1.4. Combined incubator and warmer systems;
- 3.1.5. Warmers with integrated resuscitation systems;
- 3.1.6. Transport incubators without ventilators;
- 3.1.7. Transport incubators with ventilators;
- 3.1.8. Jaundice meters; and
- 3.1.9. Neonatal Phototherapy Devices.

3.2. **Closed Incubators** within this Framework must conform to the following requirements:

- 3.2.1. **BS EN 60601-2-21:2009+A1:2016**. Medical electrical equipment. Particular requirements for the basic safety and essential performance of infant radiant warmers;
- 3.2.2. Be supplied complete with mattress and power cable suitable for use in the UK;
- 3.2.3. Display humidity levels and air temperature;
- 3.2.4. Include acoustic alarms;
- 3.2.5. Have a mobile base with secure locking mechanism;
- 3.2.6. Be height adjustable; and
- 3.2.7. Be able to tilt.

3.3. **Radiant warmers with beds** within this Framework must conform to the following requirements:

3.3.1. **BS EN 60601-2-21:2009+A1:2016**. Medical electrical equipment. Particular requirements for the basic safety and essential performance of infant radiant warmers;
3.3.2. Where the unit does not include an overhead warmer, the mattress must be a warming mattress or have the ability to be warmed;
3.3.3. Be supplied complete with mattress and power cable suitable for use in the UK;
3.3.4. Be supplied complete with the bed;
3.3.5. Display the temperature of the device;
3.3.6. Include acoustic alarms;
3.3.7. Include visual alarms;
3.3.8. Be height adjustable; and
3.3.9. Be able to tilt.

3.4. **Radiant warmers without beds** within this Framework must conform to the following requirements:
3.4.1. **BS EN 60601-2-21:2009+A1:2016**. Medical electrical equipment. Particular requirements for the basic safety and essential performance of infant radiant warmers;
3.4.2. Be supplied complete with power cable suitable for use in the UK;
3.4.3. Display the temperature of the device;
3.4.4. Include visual alarms;
3.4.5. Include acoustic alarms; and
3.4.6. Be height adjustable or suitable for use with a height adjustable bed underneath.

3.5. **Combined incubator and warmer systems** within this Framework must conform to the following requirements:
3.5.1. Must offer the functionality to be used both as a closed incubator or radiant warmer, depending on clinical need
3.5.2. Have a mobile base with secure locking mechanism;
3.5.3. Be supplied complete with mattress and power cable suitable for use in the UK;
3.5.4. Display humidity levels and incubator temperature;
3.5.5. Include acoustic alarms;
3.5.6. Include visual alarms;
3.5.7. Be height adjustable; and
3.5.8. Be able to tilt.

3.6. **Warmers with integrated resuscitation systems** within this framework must conform to the following requirements:
3.6.1. **BS EN 60601-2-21:2009+A1:2016**. Medical electrical equipment. Particular requirements for the basic safety and essential performance of infant radiant warmers;
3.6.2. Be supplied complete with mattress and power cable suitable for use in the UK;

3.6.3. Display the temperature of the device;
3.6.4. Include audible alarms;
3.6.5. Be height adjustable;
3.6.6. Include an oxygen and air-blender;
3.6.7. Include oxygen and air hoses to enable connection to a mains air supply;
3.6.8. Be capable of supplying a set flow of oxygen or blended air, and be capable of connecting to either a T-piece or bag and mask; and
3.6.9. Include a suction system for neonatal use.

3.7. **Transport incubators without ventilators** within this Framework must conform to the following requirements:
3.7.1. **BS EN IEC 60601-2-20:2020**. Medical electrical equipment. Particular requirements for the basic safety and essential performance of infant transport incubators.
3.7.2. When required for use in an air ambulance this must include a restraint as per **BS EN 13718-1:2014+A1:2020** Medical vehicles and their equipment. Air ambulances. Requirements for medical devices used in air ambulances.
3.7.3. Be suitable for transporting neonates outside hospital environments for example by ambulance or air ambulance;
3.7.4. Be supplied complete with mattress and power cable suitable for use in the UK;
3.7.5. Display the incubator air temperature;
3.7.6. Include audible and visual alarms;
3.7.7. Have a minimum 90 minutes battery life; and
3.7.8. Include a mechanism to secure the neonate in the incubator.

3.8. **Transport incubators with ventilators** within this Framework must conform to the following requirements:
3.8.1. **BS EN IEC 60601-2-20:2020**. Medical electrical equipment. Particular requirements for the basic safety and essential performance of infant transport incubators;
3.8.2. **BS EN ISO 80601-2-12:2020**. Medical electrical equipment. Particular requirements for basic safety and essential performance of critical care ventilators;
3.8.3. **BS ISO 80601-2-84:2020** Medical electrical equipment. Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment;
3.8.4. Be suitable for transporting neonates outside hospital environments by ambulance and/or air ambulance;
3.8.5. Be supplied complete with mattress and power cable suitable for use in the UK;
3.8.6. Display the incubator air temperature;
3.8.7. Include audible and visual alarms;
3.8.8. Include a mechanism to secure the neonate in the incubator; and

3.8.9. Have a minimum 90 minutes battery life.

3.8.10. The ventilator aspect of the transport incubator with ventilator product must conform to the following requirements:

3.8.11. Include a full range of audible and visual alarms for;

3.8.11.1.1. Peak inspiratory pressure (high and low);

3.8.11.1.2. Low CPAP/PEEP (Continuous Positive Airway Pressure/Positive End Expiratory Pressure);

3.8.11.1.3. Fault;

3.8.11.1.4. Gas supply loss;

3.8.11.1.5. Power failure;

3.8.11.1.6. Vent inoperative; and

3.8.11.1.7. Low battery.

3.8.12. When audible alarms are temporarily silenced, a visual display must indicate which alarm is disabled;

3.8.13. Where alarm volume is adjustable it must not be possible to turn the volume down permanently;

3.8.14. Visual alarms to be identifiable;

3.8.15. Visual alarms must be specific to the problem and remain active until the condition is corrected;

3.8.16. It must not be possible to turn off visual alarms permanently;

3.8.17. Have a backup battery or integrated power backup of a minimum of 30 minutes;

3.8.18. The ventilator must provide as a minimum standard 10-120 breaths per minute;

3.8.19. The ventilator must have VTV (volume-targeted ventilation) or IPPV (intermittent positive pressure ventilation) with 2ml to 250ml tidal volume;

3.8.20. Be capable of ventilation of neonatal patients;

3.8.21. Offer IMV (Intermittent Mandatory Ventilation) and CPAP (Continuous Positive Airway Pressure);

3.8.22. Offer a full range of controls to include;

3.8.22.1. Respiratory rate;

3.8.22.2. Fractional concentration or inspired oxygen (FiO2);

3.8.22.3. Ability to set inspiratory flow; and

3.8.22.4. Pressure limit.

3.8.23. Offer a full range of monitors to include;

3.8.23.1. Airway pressure;

3.8.23.2. Respiratory rate or inspiratory and expiratory times;

3.8.23.3. I:E ratio (Inspiratory: Expiratory);

3.8.23.4. Fractional concentration or inspired oxygen (FiO2);

3.8.23.5. PIP (Peak Inspiratory Pressure); and

3.8.23.6. PEEP (Positive End Expiratory Pressure).

3.8.24. The shell and monitor must be cleanable and compatible with both reusable and disposable consumables and attachments.

3.9. **Jaundice Meters** within this Framework must conform to the following requirements:

3.9.1. Facilitate non-invasive measurement of the neonate's bilirubin levels;

3.9.2. Suitable for hospital and community settings;

3.9.3. Be a handheld device. For the purpose of this specification 'handheld' is defined as a portable meter that is compact enough to be used or operated whilst being held in the hand or hands;

3.9.4. Include an internal power source which must not be mains powered. The system can be rechargeable; and

3.9.5. Contact parts must be either disposable or cleanable to facilitate infection control.

3.10. **Neonatal Phototherapy Devices** within this Framework must conform to the following requirements:

3.10.1. **BS EN 60601-2-50:2009+A1:2016** Medical electrical equipment. Particular requirements for the basic safety and essential performance of infant phototherapy equipment;

3.10.2. Be capable of treating hyperbilirubinemia through the application of light at blue or green wavelengths; and

3.10.3. Where a system has a base it must be mobile, have a secure locking mechanism and allow for height adjustment.

4. Lot 2 – Adult and Paediatric Phototherapy Devices and Associated Accessories

4.1. The adult and paediatric phototherapy device is a form of treatment where fluorescent light bulbs are used to treat skin conditions. Products within this lot include:

4.1.1. Full body fluorescent UV phototherapy systems; and

4.1.2. Hand & foot phototherapy systems.

4.2. **Full Body Fluorescent UV Phototherapy Systems** within this Framework must conform to the following requirements:

4.2.1. Must have a minimum designated patient irradiance (DPI) of 5 mWcm-2 for NB-UVB and 12 mWcm-2 for broadband UVA at commissioning;

4.2.2. Must offer variation in irradiance at different body positions of less than 20%;

4.2.3. Integrated UV dosimetry that accurately determines DPI and / or designated patient dose (DPD) with various body sizes. The ability for local technical user to adjust integrated dosimetry;

4.2.4. Must be able to provide real time feedback of dosimetry;

4.2.5. Have an operating temperature range 15°C to 35°C;

4.2.6. Must offer the ability for patient's UV exposure to be input as a dose (radiant exposure) or exposure time (seconds);

4.2.7. Must have a password or key operation to prevent unauthorised access;

4.2.8. Must offer temperature regulation within treatment device;

4.2.9. Must offer protection to prevent patient harm from lamp breakage;
4.2.10. Must have handle/s inside the treatment device;
4.2.11. Must have the ability to replace the lamp/s;
4.2.12. Must have controls to limit UVR exposure of individuals out with treatment device including prevention of operation unless intended operating conditions are met;
4.2.13. Must offer the ability to view the patient during treatment;
4.2.14. Must offer sensor checking and alarm to detect sensor malfunctions and automatically stops the device;
4.2.15. Must have a noise level < 70 dB;
4.2.16. Must able to identify lamp failure;
4.2.17. Must offer guaranteed 2,500 hours or 10 years of phototherapy treatment;
4.2.18. Must have the ability to measure the lifetime of the lamps and reset following a lamp change; and
4.2.19. The lamp must have an expected life of at least 500 hours.

4.3. **Hand & Foot Phototherapy Systems** within this Framework must conform to the following requirements:
4.3.1. Must have a minimum irradiance on the skin of 6 mWcm-2 for NB-UVB and 12 mWcm-2 broadband UVA for both palmar / plantar and dorsal surface;
4.3.2. Must offer variation in irradiance at different body positions of less than 20%;
4.3.3. Must have controls to limit UVR exposure of individuals out with treatment device including prevention of operation unless intended operating conditions are met;
4.3.4. Have an operating temperature range 15°C to 35°c;
4.3.5. Must have the ability to replace the lamp/s;
4.3.6. Must offer a delayed start mode;
4.3.7. Must have a password or key operation to prevent unauthorised access;
4.3.8. Must offer protection to prevent patient harm from lamp breakage;
4.3.9. Must offer the ability for patient's UV exposure to be input as a dose (radiant exposure) or exposure time (seconds);
4.3.10. Must offer programmable UV dosimetry that accurately determines irradiance and / or dose incident on dorsal and volar of hands and feet;
4.3.11. Must be able to offer automatic system checks that detects malfunctions and stops system operation;
4.3.12. Must provide detail of internal check including tube calibration;
4.3.13. Must offer guaranteed 2,500 hours or 10 years of phototherapy treatment;
4.3.14. Must offer temperature regulation within treatment device; and
4.3.15. The lamp must have an expected life of at least 500 hours.

5. Lot 3 - Neonatal Deceased Cooling System and Associated Accessories

5.1. A neonatal deceased cooling system is a cooling mattress that stops the neonate's body deteriorating and can be placed in a cot/moses basket. The neonatal deceased cooling system is placed in any Moses basket, crib, bed or another receptacle and is connected by an insulated hose and cooled.