Department of Health and Human Services
Indian Health Service

Statement of Work (SOW)
Optical Coherence Tomography with Angiography

1. PURPOSE OF THE PROJECT

The Indian Health Service (IHS), a federal agency within the Department of Health and Human Services, is responsible for providing federal health services to American Indians and Alaska Natives. The mission of IHS is to raise the physical, mental, social, and spiritual health of American Indians and Alaska Natives to the highest level and assure that comprehensive, culturally acceptable personal and public health services are available and accessible to members of the 574 federally recognized Tribes across the United States.

The Lawton Service Unit is a Joint Commission accredited federal facility in Oklahoma. To meet our mission, Optical Coherence Tomography with Angiography is a medical modality that has been deemed necessary to augment the services as such are necessary to support and supplement health care within the hospital/clinic. The mission of the Lawton Service Unit is to deliver quality care in order to attain positive health outcomes for all our valued patients with emphasis on cultural sensitivity and human dignity.

The Lawton Service Unit (LSU) which includes the Lawton Indian Hospital (LIH), Anadarko Indian Clinic (AIC), and the Carnegie Indian Clinic (CIC), Indian Health Services (IHS) has a requirement for the acquisition of an Optical Coherence Tomographer (OCT) with Angiography to replace the existing device which has reached end-of-life and is no longer serviceable. The OCT addresses a critical clinical need for high-resolution, rapid retinal imaging used in the diagnosis and monitoring of glaucoma, diabetic macular edema, macular degeneration, and other ocular pathologies. Without a functional OCT, the facility's ability to provide timely, accurate ophthalmic diagnostics and disease management for the IHS patient population is significantly impaired.

2. DETAILED DESCRIPTION OF THE TECHNICAL REQUIREMENTS

2.1. The contractor shall provide qty of 2: OCT systems with angiography, delivery, installation, configuration, and on-site user training at LIH and AIC.

2.2. Imaging Performance

- 2.2.1. Spectral-domain OCT with angiography capability, like or equal to Zeiss Cirrus-6000.
- 2.2.2. Minimum scan speed: 100,000 A-scans/second.
- 2.2.3. OCT Angiography fields: single-shot cubes supporting 3×3 mm, 6×6 mm, 8×8 mm, and up to at least 12×12 mm; optic nerve head OCTA supported.
- 2.2.4. High-definition macular and optic nerve head imaging with motion-tracking to reduce artifacts.
- 2.2.5. Anterior segment imaging, including wide angle-to-angle visualization and measurement tools (e.g., AOD/TISA), and 9 mm epithelial/pachymetry mapping.
- 2.2.6. Quantitative OCTA metrics for macula and ONH (e.g., vessel density, perfusion density, FAZ, capillary flux index) for progression tracking.
- 2.2.7. Axial resolution ≤ 5 µm (in tissue); transverse resolution ≤ 15 µm (in tissue) or better.
- 2.2.8. Minimum pupil diameter requirement ≤ 2.0 mm.

2.3. Interoperability & Data

- 2.3.1. DICOM-compliant image/data exchange with support for compressed transfer (e.g., JPEG2000/JPEG baseline) over TLS 1.2.

2.3.2. Ability to review legacy OCT data from prior generations for continuity of care, and support for data migration/centralization to an imaging server when available.
2.3.3. Local database encryption and rapid backup/restore capability.

2.4. Accessories & Software
2.4.1. System cart/table, HD monitor, keyboard/mouse, operator and service manuals.
2.4.2. Clinical applications for retina, glaucoma, and anterior segment analysis, including change/progression tools.
2.4.3. Any licenses necessary to meet the above performance requirements.
2.4.4. The imaging device must be capable of Operating System Security Updates such as Windows 11 operating system or Windows 10 IoT Enterprise LTSC 2021 or equivalent Windows Operating System with a Microsoft Lifecycle end date of no earlier than Jan 13, 2032.

3. PERIOD OF PERFORMANCE

3.1. Delivery, installation, configuration, training, and government acceptance shall be completed within 90 calendar days of award.

4. LEVEL OF EFFORT

4.1. The contractor shall furnish and install one (1) complete Optical Coherence Tomography (OCT) system with Angiography, equal to or equivalent to the Zeiss CIRRUS 6000, including all required accessories, software, and integration components necessary for full functionality and clinical use at 2 different locations.
4.1.1. Hours of Operation: Normal service hours are Monday through Friday, 8:00 a.m. – 5:00 p.m. CST, excluding federal holidays.
4.1.2. Installation Timeline: Delivery, installation, configuration, and Government acceptance shall be completed within 90 calendar days from the date of contract award.
4.1.3. Installation Duration: On-site installation and setup are expected to require 1–2 business days, including calibration and Biomedical Engineering/IT validation.
4.1.4. Testing and Validation: Post-installation performance verification and acceptance testing will be coordinated with Biomedical Engineering and IT staff and are expected to require 4–6 hours.

4.2. The contractor shall:
4.2.1. Provide all necessary personnel, materials, tools, and equipment to complete installation, testing, and training.
4.2.2. Coordinate with the Government POC to schedule delivery and installation to minimize clinical disruption.
4.2.3. Provide one-year warranty coverage for all parts, labor, and on-site service calls within 48 hours of notification of needed repair or malfunction.
4.2.4. Deliver all associated software licenses, documentation, and updates at the time of installation.
4.2.5. Ensure the OCT system is fully operational, meets all technical requirements (as defined in Section 2), and is validated by Biomedical Engineering and IT staff prior to turnover.
4.2.6. Provide remote and telephone technical support as part of the standard manufacturer warranty.
4.2.7. Include all costs for freight, delivery, setup, and demonstration in the firm-fixed total price.

4.3. Training: The contractor shall provide on-site, instructor-led training at the Lawton Service Unit immediately following installation and verification. Training shall be designed for both clinical and technical personnel and shall include, at a minimum:

4.3.1. Clinical Operations Training:
4.3.1.1. Basic operation of the OCT and Angiography functions.
4.3.1.2. Patient positioning, image acquisition, scan optimization, and data review.
4.3.1.3. Review of built-in analysis tools for retinal and glaucoma assessment.
4.3.1.4. Data storage, retrieval, and report generation workflows.
4.3.2. Technical/IT/Biomedical Training:
4.3.2.1. System startup and shutdown procedures.
4.3.2.2. Software configuration, networking, and data backup.
4.3.2.3. Routine maintenance and troubleshooting procedures.
4.3.2.4. Review of cybersecurity settings, user access controls, and DICOM integration.
4.3.2.5. The contractor shall provide training materials/manuals to the Government POC upon completion. Refresher training or follow-up sessions, if needed within the warranty period, shall be provided at no additional cost to the Government.

5. SPECIAL REQUIREMENTS

5.1. In accordance with HHSAR 304.1300(b) non-routine contractor employees shall comply with OPDIV DHHS/SE Region – Human Resources, Security Clearance Guidance – Visitors (3/29/12) policy for contract performance period. Contractor employees will be required to obtain a visitor's pass upon arrival for services from Facilities Management. - (Security Clearance for on-site human services)

5.2. The USPHS Lawton Service Unit is a tobacco/smoke free environment (buildings and grounds). No tobacco/smoking use will be tolerated during service.

5.3. Security Requirements: Contractor personnel will be required to contact the government designated point of contact upon arrival when reporting for service calls or delivery supplies. The contractor shall be responsible for the security of all organizational information. Current rules and regulations applicable to the premises, where the work shall be performed shall apply to the contractor and its employees while working on the premises. These regulations include but are not limited to, escort by Lawton Service Unit official, presenting valid identification, smoking restriction and any safety procedures.

5.4. The contractor shall not disclose or cause to disseminate any information concerning operations of Lawton Service Unit. Such action(s) could result in violation of the contract and possible legal actions.

5.4.1. All inquiries, comments, or complaints arising from any matter observed, experienced or learned of as a result of or in connection with the performance of the contract, the resolution of which may require the dissemination of official information, shall be directed to the government's designated representative.

6. SECTION 508/ACCESSIBILITY

6.1. This product must conform to the Revised Section 508 (https://www.access-board.gov/guidelines-and-standards/communications-and-it/about-the-ict-refresh/final-rule/text-of-the-standards-and-guidelines) and WCAG 2.1 Level AA standards as outlined below.
6.2. Solicitations for supplies and services shall require the submission of a Section 508 Product Assessment Template. The template can be found at https://www.itic.org/policy/accessibility/vpat.

6.3. All Information and Communication Technology (ICT) deliverables under this contract (e.g., websites, applications, electronic documents, and multimedia) must comply with the Revised Section 508 Standards (36 CFR Part 1194) and the Web Content Accessibility Guidelines (WCAG) 2.1 Level AA standards. The Contractor shall ensure accessibility of all ICT deliverables and provide conformance documentation in the form of a Voluntary Product Accessibility Template (VPAT®) / Accessibility Conformance Report (ACR), or by completing the HHS Section 508 Accessibility Checklists. The current VPAT 2.5 template includes fields for reporting conformance to WCAG 2.1 and shall be used to document accessibility. The Contractor shall remediate any identified accessibility issues at no additional cost. The Contracting Officer will include the applicable Health and Human Services Acquisition Regulation (HHSAR) clauses 352.239-73 and 352.239-74 in the solicitation and resulting contract.

7. PRIVACY AND INDEMNIFICATION CLAUSES

7.1. The contractor will comply with the following listed regulations:

- 7.1.1. Privacy Act, 5 U.S.C. Office of Privacy and Civil Liberties | Privacy Act of 1974
- 7.1.2. Health Insurance Portability and Accountability Act (HIPAA) - eCFR :: 45 CFR Part 164 -- Security and Privacy
- 7.1.3. CFR 42 Part 2 - eCFR :: 42 CFR Part 2 -- Confidentiality of Substance Use Disorder Patient Records

7.2. Indemnification and Governing Law

- 7.2.1. Indemnification, Liability, Statute of Limitations: Any provisions in the Terms of Service (TOS) related to indemnification and filing deadlines are hereby waived, and shall not apply except to the extent expressly authorized by law. Liability for any breach of the TOS as modified by this amendment, or any claim arising from the TOS as modified by this amendment, shall be determined under the Federal Tort Claims Act, or other governing federal authority. Federal statute of limitations provisions shall apply to any breach or claim.
- 7.2.2. Governing law: Any arbitration, mediation or similar dispute resolution provision in the TOS is hereby deleted. The TOS and this amendment shall be governed by and interpreted and enforced in accordance with the laws of the United States of America without reference to conflict of laws. To the extent permitted by federal law, the laws of the State of Oklahoma will apply in the absence of applicable federal law.

8. DELIVERABLES AND REPORTING REQUIREMENTS

8.1. Delivery: The contractor will coordinate the delivery, installation and training date with the designated government employee. No deliveries can be made after 4:00pm. Driver needs a valid ID. The contractor shall deliver as outlined in section 2 to each location as below:

- 8.1.1. Anadarko Indian Health Center at 201 E Parker McKenzie Dr Anadarko, OK 73005 with all installation instructions, warranty documents, and specifications.
- 8.1.2. Lawton Indian Hospital at 1515 Lawrie Tatum Rd, Lawton OK 73507 with all installation instructions, warranty documents, and specifications.

8.2. Contractor Point of Contact: The contractor shall furnish one designated point of contact (POC) to the government's designated representative for coordination of supplies, delivery, and/or maintenance. The

POC will be empowered to make daily decisions to ensure that the contract implementation and day-to-day maintenance meets the terms and conditions of this contract.

8.3. Contractor's Phone Numbers: The contractor shall provide a toll-free telephone number for service calls, which must be answered during at least eight working hours, between 8:00 am and 4:30 pm, Monday through Friday.

9. GOVERNMENT FURNISHED PROPERTY, FACILITIES AND SERVICES

9.1. IAW FAR Part 52.245-1, The Government shall supply the facilities, supplies and the equipment of the Optometry Department and all hospital specialty/support staff. Use of government furnished facility space, equipment, supplies, and personnel are for the provision of services set forth in this contract only.

10. CONTRACTOR FURNISHED PROPERTY, FACILITIES AND SERVICES

10.1. Required personnel, materials, supplies and equipment: The contractor shall furnish all personnel, materials, supplies and equipment required to perform work under the contract.

11. CHANGES TO THE STATEMENT OF WORK (SOW)

11.1. Any changes to this SOW shall be authorized and approved only through written correspondence from the Contracting Officer. Costs incurred by the contractor through the actions of parties other than the Contracting Officer shall be borne by the contractor.

12. DELIVERABLES/PERFORMANCE MATRIX

12.1. Equipment and Software Deliverables (for each location)

- 12.1.1. One (1) complete OCT system with Angiography, including all required software, imaging modules, and hardware accessories for operation.
- 12.1.2. System shall include:
  - 12.1.2.1. Main OCT imaging unit with built-in fundus alignment camera or line-scanning ophthalmoscope.
  - 12.1.2.2. Computer workstation with preinstalled OCT software and database.
  - 12.1.2.3. Monitor, keyboard, mouse, and motorized table.
  - 12.1.2.4. Power cords, network cables, and accessories necessary for operation.
  - 12.1.2.5. Two (2) operator manuals and two (2) service manuals (digital or printed).
  - 12.1.2.6. One-year manufacturer warranty covering parts, labor, and remote support.
- 12.1.3. Software shall include applications for:
  - 12.1.3.1. Retinal layer segmentation and change analysis.
  - 12.1.3.2. Ganglion cell/inner plexiform layer (GCL/IPL) and optic nerve head (ONH) analysis.
  - 12.1.3.3. OCT Angiography with quantitative metrics (vessel density, perfusion density, FAZ, etc.).
  - 12.1.3.4. Anterior segment imaging, pachymetry, and angle analysis tools.

12.2. Installation and Configuration Deliverables (for each location)

12.2.1. Contractor shall provide on-site setup, calibration, and configuration in coordination with Biomedical Engineering and IT personnel.
12.2.2. A completed Installation and Validation Checklist shall be submitted to the Government POC upon installation.
12.2.3. The system must be fully operational and validated for clinical use before acceptance.

12.3. Training Deliverables (for each location)
12.3.1. On-site user training for clinical and technical staff immediately following installation.
12.3.2. Minimum of one (1) day of structured training, divided into clinical and technical sessions.
12.3.3. Training shall include patient imaging workflow, data management, maintenance, and troubleshooting.

12.4. Training deliverables: (for each location)
12.4.1. Electronic copies of training materials and reference guides.
12.4.2. Summary of topics covered and certification of completion.

12.5. Documentation Deliverables (for each location)
12.5.1. User manuals and service manuals (two copies each, digital or printed).
12.5.2. Manufacturer warranty and support policy documentation.
12.5.3. Technical data sheets and cybersecurity configuration summary.
12.5.4. Completed Installation/Acceptance Report signed by the Contractor and Government POC.
12.5.5. Any software license documentation or activation keys (if applicable).

12.6. Completion Criteria (for each location)
12.6.1. The deliverables shall be considered complete when:
12.6.1.1. The OCT system is installed, configured, and operational.
12.6.1.2. Biomedical Engineering and IT verify functional performance and cybersecurity compliance.
12.6.1.3. End-user training is completed and documented.
12.6.1.4. The Government POC signs the final acceptance report.

Upon acceptance, the contractor's responsibilities will transition to warranty support for the remainder of the coverage period.

6/23/2026

X Randy Cox

Randy Cox
Chief of Optometry
Signed by: PIV