

Public notice of a proposed contract action less than \$25,000.00

The United States Food and Drug Administration (FDA)

XFDTD Annual Support for Licenses

REMCOM XFDTD Brand Name Requirement

Statement of Work (SOW)

1. Background

The Electromagnetics and Wireless Laboratory (EMW) in the FDA's Center for Devices and Radiological Health, Office of Science and Engineering Laboratories (OSEL), Division of Biomedical Physics (DBP) is, among other things, responsible for analyzing the exposure of people – patients, medical care providers and the public – to sources of electromagnetic radiation. Our primary tools in these analyses are computer simulations using high resolution models of the human body. The software we use to perform these simulations is XFDTD. XFDTD is a computational modeling software suite that is used to calculate and visualize the behavior of three-dimensional (3D) models of medical devices and people when they are exposed to electromagnetic (EM) fields. XFDTD is used extensively in numerous investigations which include:

- 1) Magnetic Resonance Imaging (MRI) safety
- 2) Electromagnetic compatibility (EMC)
- 3) Human exposure to electromagnetic fields from sources such as cell phones, metal detectors, and Radio Frequency Identification (RFID)

Continued software upgrades and technical support are essential for the continuation of these investigations. CDRH/OSEL/DBP owns two XFDTD licenses. The objective of this requisition is to obtain hotline and upgrade support for our two XFDTD licenses.

2. Objectives

The objective is to obtain software support services for REMCOM licenses.

3. Scope

The Food and Drug Administration requires maintenance services (hotline and upgrade support) on our three SEMCAD/SIM4LIFE licenses. In addition to the basic REMCOM modules (GUI and FDTD) each license has different software and GPU acceleration options. The vendor will supply online and phone support for the resolution of technical questions that the end user may encounter during the period of service. The vendor will supply any periodic updates and bug fixes that are released during the period of service.

4. Period of Performance

The maintenance on all three licenses will extend from 8/9/2020 to 8/8/2021.

5. Specific Tasks/Deliverables

The Food and Drug Administration requires maintenance services (hotline and upgrade support) on our two XFDTD licenses with GPU acceleration options.

The vendor will supply online and phone support for the resolution of technical questions that the end user may encounter during the period of service. The vendor will supply any periodic updates and bug fixes that are released during the period of service.

- Within ten (10) days after contract award, the vendor shall supply to the COR a confirmation that the maintenance support has been delivered to the FDA

6. Place of Performance

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7. Delivery Schedule

Deliverables and schedule will be coordinated by the COR. Delivery is anticipated within 10 days of award.

8. Pricing Table/ Specific Parts Numbers

Pricing Table:

ITEM #	PART #	DESCRIPTION	QUANTITY	UNIT PRICE	DISCOUNT	EXTENDED PRICE
1	XFRPS	XFtd Pro Package : Node-Locked Perpetual product upgrades and support	2			
2	XFRPS	XFtd HPC Token : Node-Locked Perpetual product upgrades and support	1			
					TOTAL PRICE:	

9. Security

Pursuant to Federal and HHS Information Security Program Policies, the contractor and any subcontractor performing under this task order shall comply with the following requirements:

Federal Information Security Management Act of 2002 (FISMA), Title III, E-Government Act of 2002, Pub. L. No. 107-347 (Dec. 17, 2002); <http://csrc.nist.gov/policies/FISMA-final.pdf>.

- *Information Type*

[X] *Administrative, Management and Support Information:*

*Information Management
Lifecycle/ Change Management
Reporting and Information*

- *Contractor-Employee Non-Disclosure Agreements*
Each contractor/subcontractor employee who may have access to non-public Department information under this task order shall complete the Commitment to Protect Non-Public Information - Contractor Agreement (http://nitaac.nih.gov/downloads/ciosp2/Contractor_Employee_Non-Disclosure.doc). A copy of each signed and witnessed Non-Disclosure agreement shall be submitted to the Project Officer prior to performing any work under the contract.
- *Confidential Treatment of Sensitive Information*
The Contractor shall guarantee strict confidentiality of the information/data that it is provided by the Government during the performance of the task order. The Government has determined that the information/data that the Contractor will be provided during the performance of the task order is of a sensitive nature.

Disclosure of the information/data, in whole or in part, by the Contractor can only be made after the Contractor receives prior written approval from the Contracting Officer. Whenever the Contractor is uncertain with regard to the proper handling of information/data under the contract, the Contractor shall obtain a written determination from the Contracting Officer.

10. Government Furnished Equipment (GFE)/ Government Furnished Information (GFI)

No GFE will be required in support and execution of this procurement.

11. Inspection and Acceptance Criteria

Requirements for inspection and acceptance are as follows:

- Inspection will include validation of maintenance agreements, patches and upgrades delivered.
- All upgrades, patches or maintenance activities will be inspected by the FDA operational team for final acceptance.
- The Government will provide written notification of acceptance or rejection within ten (10) business days of receiving the service.
- The Government will reject non-conforming services. The Contractor shall correct any deficiencies within thirty (30) days of when the Government issues the rejection notice. If the Contractor cannot correct the deficiencies within this time frame, the Contractor shall immediately notify the COR or technical POC of the reason for the delay and provide a proposed corrective action plan within ten (10) business days.

12. Other Pertinent Information or Special Considerations

The Contractor should be familiar with Section 508 requirements as described at <http://www.section508.gov/> in order to ensure that software currently installed in FDA systems remain in compliance.

13. 508 Standard Compliance

Electronic and Information Technology Accessibility Notice (December 18, 2015)

(a) Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that when Federal agencies develop, procure, maintain, or use electronic and information technology, Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities, unless an undue burden would be imposed on the agency. Section 508 also requires that individuals with disabilities, who are members of the public seeking information or services from a Federal agency, have access to and use of information and data that is comparable to that provided to the public who are not individuals with disabilities, unless an undue burden would be imposed on the agency.

(b) The software currently installed in the FDA's systems is in compliance with Section 508 requirements. The contractor shall maintain the licenses and support so that they remain in compliance.

(c) Information about Section 508 is available at <http://www.hhs.gov/web/508>. The complete text of the Section 508 Final Provisions can be accessed at <http://www.access-board.gov/guidelines-and-standards/communications-and-it/about-the-section-508-standards>.

14. FDA Points of Contact

Contracting Officer:

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15. Contracting Officer Authority

The Contracting Officer (CO) is the sole person authorized to make or approve any changes in any of the requirements of this purchase order and notwithstanding any provisions contained elsewhere in the order, the said authority remains solely with the CO. In the event the Vendor makes any changes at the direction of any person other than the CO, the change shall be considered to have been made without authority and no adjustment will be made in the order terms and conditions, including price. The CO shall be the only individual authorized to accept nonconforming work, waive any requirement of the order and modify any term or condition of the order. The CO is the only individual who can legally obligate Government funds.

The Contracting Officer's Representative (COR) or Project Officer is not authorized to make any commitments or otherwise obligate the Government or authorize any changes which affect the order price, terms or conditions. The COR/Project Officer is responsible for the technical aspects of the project and serves as technical liaison with the Vendor and is responsible for the final inspection and acceptance, and such other responsibilities as may be specified in the purchase order.

16. Order of Precedence

The Vendor shall follow the terms and conditions of this order. Should the Vendor include any additional terms and conditions resulting in conflicts between this document and the Contractor's document, the Order of Precedence shall be as specified in FAR Clause 52.212-4 - Contract Terms and Conditions - Commercial Items (Jan 2017). Any indemnification language

indemnifying the Contractor of any liability and governing law language in the Contractor's terms and conditions shall be null and void in this order. Any additional terms and conditions shall not be prohibited by applicable laws and regulations. Any additional terms and conditions identified with a web link and/or incorporated by reference shall be null and void.

17. Clauses

FAR CLAUSES:

52.212-4 Contract Terms and Conditions-Commercial Items (Oct 2018)

52.212-5 Contract Terms and Conditions Required To Implement Statutes or Executive Orders Commercial Items (May 2019)

(a) The Contractor shall comply with the following Federal Acquisition Regulation (FAR) clauses, which are incorporated in this contract by reference, to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

(1) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017)

(section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

(2) 52.209-10, Prohibition on Contracting with Inverted Domestic Corporations (Nov 2015).

(3) 52.233-3, Protest After Award (Aug 1996) (31 U.S.C. 3553).

(4) 52.233-4, Applicable Law for Breach of Contract Claim (Oct 2004)(Public Laws 108-77 and 108-78 (19 U.S.C. 3805 note)).

(b) The Contractor shall comply with the FAR clauses in this paragraph (b) that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

[Contracting Officer check as appropriate.]

___ (1) 52.203-6, Restrictions on Subcontractor Sales to the Government (Sept 2006), with Alternate I (Oct 1995) (41 U.S.C. 4704 and 10 U.S.C. 2402).

___ (2) 52.203-13, Contractor Code of Business Ethics and Conduct (Oct 2015) (41 U.S.C. 3509)).

___ (3) 52.203-15, Whistleblower Protections under the American Recovery and Reinvestment Act of 2009 (June 2010)

(Section 1553 of Pub. L. 111-5). (Applies to contracts

funded by the American Recovery and Reinvestment Act of 2009.)

XX (4) 52.204-10, Reporting Executive Compensation and First-Tier Subcontract Awards (Oct 2016) (Pub. L. 109-282) (31 U.S.C. 6101 note).

___ (5) [Reserved].

___ (6) 52.204-14, Service Contract Reporting Requirements Oct 2016) (Pub. L. 111-117, section 743 of Div. C).

___ (7) 52.204-15, Service Contract Reporting Requirements for Indefinite-Delivery Contracts (Oct 2016) (Pub. L. 111-117, section 743 of Div. C).

XX (8) 52.209-6, Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment. (Oct 2015) (31 U.S.C. 6101 note).

___ (9) 52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters (Jul 2013) (41 U.S.C. 2313).

- ___ (10) [Reserved].
- ___ (11)(i) 52.219-3, Notice of HUBZone Set-Aside or Sole-Source Award (Nov 2011) (15 U.S.C. 657a).
- ___ (ii) Alternate I (Nov 2011) of 52.219-3.
- __XX_ (12)(i) 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (Oct 2014) (if the offeror elects to waive the preference, it shall so indicate in its offer) (15 U.S.C. 657a).
- ___ (ii) Alternate I (Jan 2011) of 52.219-4.
- ___ (13) [Reserved]
- __XX_ (14)(i) 52.219-6, Notice of Total Small Business Set-Aside (Nov 2011) (15 U.S.C. 644).
- ___ (ii) Alternate I (Nov 2011).
- ___ (iii) Alternate II (Nov 2011).
- ___ (15)(i) 52.219-7, Notice of Partial Small Business Set-Aside (June 2003) (15 U.S.C. 644).
- ___ (ii) Alternate I (Oct 1995) of 52.219-7.
- ___ (iii) Alternate II (Mar 2004) of 52.219-7.
- ___ (16) 52.219-8, Utilization of Small Business Concerns (Nov 2016) (15 U.S.C. 637(d)(2) and (3)).
- ___ (17)(i) 52.219-9, Small Business Subcontracting Plan (Jan 2017) (15 U.S.C. 637(d)(4)).
- ___ (ii) Alternate I (Nov 2016) of 52.219-9.
- ___ (iii) Alternate II (Nov 2016) of 52.219-9.
- ___ (iv) Alternate III (Nov 2016) of 52.219-9.
- ___ (v) Alternate IV (Nov 2016) of 52.219-9.
- __XX_ (18) 52.219-13, Notice of Set-Aside of Orders (Nov 2011) (15 U.S.C. 644(r)).
- ___ (19) 52.219-14, Limitations on Subcontracting (Jan 2017) (15 U.S.C. 637(a)(14)).
- ___ (20) 52.219-16, Liquidated Damages Subcontracting Plan (Jan 1999) (15 U.S.C. 637(d)(4)(F)(i)).
- ___ (21) 52.219-27, Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (Nov 2011) (15 U.S.C. 657 f).
- __XX_ (22) 52.219-28, Post Award Small Business Program Representation (Jul 2013) (15 U.S.C. 632(a)(2)).
- ___ (23) 52.219-29, Notice of Set-Aside for, or Sole Source Award to, Economically Disadvantaged Women-Owned Small Business Concerns (Dec 2015) (15 U.S.C. 637(m)).
- ___ (24) 52.219-30, Notice of Set-Aside for, or Sole Source Award to, Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program (Dec 2015) (15 U.S.C. 637(m)).
- XX___ (25) 52.222-3, Convict Labor (June 2003) (E.O. 11755).
- __XX_ (26) 52.222-19, Child Labor Cooperation with Authorities and Remedies (Jan 2018) (E.O. 13126).
- __XX_ (27) 52.222-21, Prohibition of Segregated Facilities (Apr 2015).
- __XX_ (28) 52.222-26, Equal Opportunity (Sept 206) (E.O. 11246).

- ___ (29) 52.222-35, Equal Opportunity for Veterans (Oct 2015)(38 U.S.C. 4212).

- _XX_ (30) 52.222-36, Equal Opportunity for Workers with Disabilities (Jul 2014) (29 U.S.C. 793).
- __ (31) 52.222-37, Employment Reports on Veterans (Feb 2016) (38 U.S.C. 4212).
- __ (32) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496).
- _XX_ (33)(i) 52.222-50, Combating Trafficking in Persons (Mar 2015) (22 U.S.C. chapter 78 and E.O. 13627).
- __ (ii) Alternate I (Mar 2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).
- __ (34) 52.222-54, Employment Eligibility Verification (Oct 2015). (Executive Order 12989). (Not applicable to the acquisition of commercially available off-the-shelf items or certain other types of commercial items as prescribed in 22.1803.)
- __ (35)(i) 52.223-9, Estimate of Percentage of Recovered Material Content for EPA Designated Items (May 2008) (42 U.S.C. 6962(c)(3)(A)(ii)). (Not applicable to the acquisition of commercially available off-the-shelf items.)
- __ (ii) Alternate I (May 2008) of 52.223-9 (42 U.S.C. 6962(i)(2)(C)). (Not applicable to the acquisition of commercially available off-the-shelf items.)
- __ (36) 52.223-11, Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons (Jun 2016) (E.O. 13693).
- __ (37) 52.223-12, Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners (Jun 2016) (E.O. 13693).
- __ (38)(i) 52.223-13, Acquisition of EPEAT -Registered Imaging Equipment (Jun 2014) (E.O.s 13423 and 13514).
- __ (ii) Alternate I (Oct 2015) o 52.223-13.
- __ (39)(i) 52.223-14, Acquisition of EPEAT -Registered Televisions (Jun 2014) (E.O.s 13423 and 13514).
- __ (ii) Alternate I (Jun 2014) of 52.223-14.
- __ (40) 52.223-15, Energy Efficiency in Energy-Consuming Products (Dec 2007) (42 U.S.C. 8259b).
- __ (41)(i) 52.223-16, Acquisition of EPEAT-Registered Personal Computer Products (Oct 2015) (E.O.s 13423 and 13514).
- __ (ii) Alternate I (Jun 2014) of 52.223-16.
- _XX_ (42) 52.223-18, Encouraging Contractor Policies to Ban Text Messaging While Driving (Aug 2011) (E.O. 13513).
- __ (43) 52.223-20, Aerosols (Jun 2016) (E.O. 13693).
- __ (44) 52.223-21, Foams (Jun 2016) (E.O. 13693).
- __ (45)(i) 52.224-3, Privacy Training (JAN 2017) (5 U.S.C. 552a).
- __ (ii) Alternate I (JAN 2017) of 52.224-3.
- _XX_ (46) 52.225-1, Buy American Supplies (May 2014) (41 U.S.C. chapter 83).
- __ (47)(i) 52.225-3, Buy American Free Trade Agreements Israeli Trade Act (May 2014) (41 U.S.C. chapter 83, 19 U.S.C. 3301 note, 19 U.S.C. 2112 note, 19 U.S.C. 3805 note, 19 U.S.C. 4001 note, Pub. L. 103-182, 108-77, 108-78, 108-286, 108-302, 109-53, 109-169, 109-283, 110-138, 112-41, 112-42, and 112-43).
- __ (ii) Alternate I (May 2014) of 52.225-3.
- __ (iii) Alternate II (May 2014) of 52.225-3.

- ___ (iv) Alternate III (May 2014) of 52.225-3.
- ___ (48) 52.225-5, Trade Agreements (Oct 2016) (19 U.S.C. 2501, et seq., 19 U.S.C. 3301 note).
- _XX_ (49) 52.225-13, Restrictions on Certain Foreign Purchases (June 2008) (E.O.s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).
- ___ (50) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).
- ___ (51) 52.226-4, Notice of Disaster or Emergency Area Set-Aside (Nov 2007) (42 U.S.C. 5150).
- ___ (52) 52.226-5, Restrictions on Subcontracting Outside Disaster or Emergency Area (Nov 2007) (42 U.S.C. 5150).
- ___ (53) 52.232-29, Terms for Financing of Purchases of Commercial Items (Feb 2002) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).
- ___ (54) 52.232-30, Installment Payments for Commercial Items (Jan 2017) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).
- _XX_ (55) 52.232-33, Payment by Electronic Funds Transfer System for Award Management (Jul 2013) (31 U.S.C. 3332).

___ (56) 52.232-34, Payment by Electronic Funds Transfer
Other than System for Award Management (Jul 2013) (31 U.S.C. 3332).

XX (57) 52.232-36, Payment by Third Party (May 2014) (31 U.S.C. 3332).

___ (58) 52.239-1, Privacy or Security Safeguards (Aug 1996) (5 U.S.C. 552a).

___ (59) 52.242-5, Payments to Small Business Subcontractors (Jan 2017)(15 U.S.C. 637(d)(12)).

___ (60)(i) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx. 1241(b) and 10 U.S.C. 2631).

___ (ii) Alternate I (Apr 2003) of 52.247-64.

(c) The Contractor shall comply with the FAR clauses in this paragraph (c), applicable to commercial services, that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

[Contracting Officer check as appropriate.]

___ (1) 52.222-17, Nondisplacement of Qualified Workers (May 2014)(E.O. 13495).

XX (2) 52.222-41, Service Contract Labor Standards (May 2014) (41 U.S.C. chapter 67).

XX (3) 52.222-42, Statement of Equivalent Rates for Federal Hires (May 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).

XX (4) 52.222-43, Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (Multiple Year and Option Contracts) (May 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).

___ (5) 52.222-44, Fair Labor Standards Act and Service Contract Labor Standards Price Adjustment (May 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).

___ (6) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment Requirements (May 2014) (41 U.S.C. chapter 67).

___ (7) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services

Requirements (May 2014) (41 U.S.C. chapter 67).

XX (8) 52.222-55, Minimum Wages Under Executive Order 13658 (Dec 2015).

XX (9) 52.222-62, Paid Sick Leave Under Executive Order 13706 (JAN 2017) (E.O. 13706).

___ (10) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (May 2014) (42 U.S.C. 1792).

___ (11) 52.237-11, Accepting and Dispensing of \$1 Coin (Sept 2008) (31 U.S.C. 5112(p)(1)).

(d) Comptroller General Examination of Record. The Contractor shall comply with the provisions of this

paragraph (d) if this contract was awarded using other than sealed bid, is in excess of the simplified acquisition threshold, and does not contain the clause at 52.215-2, Audit and Records Negotiation.

(1) The Comptroller General of the United States, or an authorized representative of the Comptroller General, shall have access to and right to examine any of the Contractor's directly pertinent records involving transactions related to this contract.

(2) The Contractor shall make available at its offices at all reasonable times the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this contract or for any shorter period specified in FAR subpart 4.7, Contractor Records Retention, of the other clauses of this contract.

If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement. Records relating to appeals under the disputes clause or to litigation or the settlement of claims arising under or relating to this contract shall be made available until such appeals, litigation, or claims are finally resolved.

(3) As used in this clause, records include books, documents, accounting procedures and practices, and other data, regardless of type and regardless of form. This does not require the Contractor to create or maintain any record that the Contractor does not maintain in the ordinary course of business or pursuant to a provision of law.

(e)(1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c), and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in this paragraph (e)(1) in a subcontract for commercial items. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause

(i) 52.203-13, Contractor Code of Business Ethics and Conduct (Oct 2015) (41 U.S.C. 3509).

(ii) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

(iii) 52.219-8, Utilization of Small Business Concerns (Nov 2016) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds \$700,000 (\$1.5 million for construction of any public facility), the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.

(iv) 52.222-17, Nondisplacement of Qualified Workers (May 2014) (E.O. 13495). Flow down required in accordance with paragraph (l) of FAR clause 52.222-17.

(v) 52.222-21, Prohibition of Segregated Facilities (Apr 2015)

(vi) 52.222-26, Equal Opportunity (Sept 2016) (E.O. 11246).

(vii) 52.222-35, Equal Opportunity for Veterans (Oct 2015) (38 U.S.C. 4212).

- (viii) 52.222-36, Equal Opportunity for Workers with Disabilities (Jul 2014) (29 U.S.C. 793).
 - (ix) 52.222-37, Employment Reports on Veterans (Feb 2016) (38 U.S.C. 4212)
 - (x) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496). Flow down required in accordance with paragraph (f) of FAR clause 52.222-40.
 - (xi) 52.222-41, Service Contract Labor Standards (May 2014) (41 U.S.C. chapter 67).
 - (xii) 52.222-50, Combating Trafficking in Persons (Mar 2015) (22 U.S.C. chapter 78 and E.O 13627). Alternate I (Mar 2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O 13627).
 - (xiii) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (May 2014) (41 U.S.C. chapter 67).
 - (xiv) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Requirements (May 2014) (41 U.S.C. chapter 67).
 - (xv) 52.222-54, Employment Eligibility Verification (Oct 2015) (E.O. 12989).
 - (xvi) 52.222-55, Minimum Wages Under Executive Order 13658 (Dec 2015).
 - (xvii) 52.222-62, Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706).
 - (xviii)(A) 52.224-3, Privacy Training (Jan 2017) (5 U.S.C. 552a).
 - (B) Alternate I (Jan 2017) of 52.224-3.
 - (xix) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).
 - (xx) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (May 2014) (42 U.S.C. 1792). Flow down required in accordance with paragraph (e) of FAR clause 52.226-6.
 - (xxi) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx. 1241(b) and 10 U.S.C. 2631). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64.
- (2) While not required, the Contractor may include in its subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

(End of clause)

FAR 52.252-2: Clauses Incorporated by Reference (Feb 1998)

This purchase order incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address:

<https://www.acquisition.gov/far/current/html/FARTOCP52.html#wp372482>

(End of Clause)

FAR 52.203-19: Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements (Jan 2017)

(a) The Contractor shall not require its employees or subcontractors to sign or comply with internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting waste, fraud, or abuse related to the performance of a Government contract to a designated investigative or law enforcement

representative of a Federal department or agency authorized to receive such information (e.g., agency Office of the Inspector General).

(b) The Contractor shall notify current employees and subcontractors that prohibitions and restrictions of any preexisting internal confidentiality agreements or statements covered by this clause, to the extent that such prohibitions and restrictions are inconsistent with the prohibitions of this clause, are no longer in effect.

(c) The prohibition in paragraph (a) of this clause does not contravene requirements applicable to Standard Form 312 (Classified Information Nondisclosure Agreement), Form 4414 (Sensitive Compartmented Information Nondisclosure Agreement), or any other form issued by a Federal department or agency governing the nondisclosure of classified information.

(d) In accordance with section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015, (Pub. L. 113-235), and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions) use of funds appropriated (or otherwise made available) is prohibited, if the Government determines that the Contractor is not in compliance with the provisions of this clause.

(e) The Contractor shall include the substance of this clause, including this paragraph (e), in subcontracts under such contracts.

(End of Clause)

FAR 52.232-39: Unenforceability of Unauthorized Obligations (June 2013)

FAR 52.232-40: Providing Accelerated Payments to Small Business Subcontractors (Dec 2013)

HHSAR CLAUSES:

The below Health and Human Services Acquisition Regulation (HHSAR) Clauses apply.

HHSAR Clauses can be viewed in full text at: <https://www.hhs.gov/grants/contracts/contract-policies-regulations/hhsar/index.html>

HHSAR 352.222-70 Contractor Cooperation in Equal Employment Opportunity Investigations (December 2015)

PROVISIONS:

FAR 52.252-1: Solicitation Provisions Incorporated by Reference (Feb 1998)

This solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text of those provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address:

FAR 52.203-18, Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements—Representation (January 2017)

(a) Definition. As used in this provision--

“Internal confidentiality agreement or statement”, “subcontract”, and “subcontractor”, are defined in the clause at 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements.

(b) In accordance with section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions), Government agencies are not permitted to use funds appropriated (or otherwise made available) for contracts with an entity that requires employees or subcontractors of such entity seeking to report waste, fraud, or abuse to sign internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting such waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information.

(c) The prohibition in paragraph (b) of this provision does not contravene requirements applicable to Standard Form 312, (Classified Information Nondisclosure Agreement), Form 4414 (Sensitive Compartmented Information Nondisclosure Agreement), or any other form issued by a Federal department or agency governing the nondisclosure of classified information.

(d) Representation. By submission of its offer, the Offeror represents that it will not require its employees or subcontractors to sign or comply with internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting waste, fraud, or abuse related to the performance of a Government contract to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information (e.g., agency Office of the Inspector General).

(End of provision)

HHSAR Provisions

The below Health and Human Services Acquisition Regulation (HHSAR) Provisions apply.

HHSAR Provisions can be viewed in full text at: <https://www.hhs.gov/grants/contracts/contract-policies-regulations/hhsar/index.html>

HHSAR 352.239-73: Electronic and Information Technology Accessibility Notice (Dec 2015)

(a) Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that when Federal agencies develop, procure, maintain, or use electronic and information technology, Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities, unless an undue burden would be imposed on the agency. Section 508 also requires that individuals with disabilities, who are members of the public seeking information or services from a Federal agency, have access to and use of information and data that is comparable to that

provided to the public who are not individuals with disabilities, unless an undue burden would be imposed on the agency.

(b) Accordingly, any offeror responding to this solicitation must comply with established HHS EIT accessibility standards. Information about Section 508 is available at <http://www.hhs.gov/web/508>. The complete text of the Section 508 Final Provisions can be accessed at <http://www.access-board.gov/guidelines-and-standards/communications-and-it/about-the-section-508-standards>.

(c) The Section 508 accessibility standards applicable to this solicitation are stated in the clause at 352.239-74, Electronic and Information Technology Accessibility.

In order to facilitate the Government's determination whether proposed EIT supplies meet applicable Section 508 accessibility standards, offerors must submit an HHS Section 508 Product Assessment Template, in accordance with its completion instructions. The purpose of the template is to assist HHS acquisition and program officials in determining whether proposed EIT supplies conform to applicable Section 508 accessibility standards. The template allows offerors or developers to self-evaluate their supplies and document—in detail—whether they conform to a specific Section 508 accessibility standard, and any underway remediation efforts addressing conformance issues. Instructions for preparing the HHS Section 508 Evaluation Template are available under Section 508 policy on the HHS website <http://www.hhs.gov/web/508>.

In order to facilitate the Government's determination whether proposed EIT services meet applicable Section 508 accessibility standards, offerors must provide enough information to assist the Government in determining that the EIT services conform to Section 508 accessibility standards, including any underway remediation efforts addressing conformance issues.

(d) Respondents to this solicitation must identify any exception to Section 508 requirements. If an offeror claims its supplies or services meet applicable Section 508 accessibility standards, and it is later determined by the Government, i.e., after award of a contract or order, that supplies or services delivered do not conform to the described accessibility standards, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its expense.

(End of provision)

18. Brand name Justification

This purchase is in compliance with FAR 6.302-1 "*Only one responsible source and no other supplies or services will satisfy agency requirements*". This acquisition is conducted under the authority of United States Code (U.S.C.) 10 U.S.C. 2304(c)(1) or 41 U.S.C. 3304(a)(1). Remcom, Inc. is the manufacturer, developer and only distributor of XFDTD. Remcom is the only possible source for XFDTD maintenance and technical support. XFDTD is the only computational modeling software suite that can be used to calculate and visualize the behavior of three-dimensional (3D) models of medical devices and people when they are exposed to electromagnetic (EM) fields. XFDTD must be used extensively in numerous FDA CDRH/OSEL investigations.

19. Instructions to Offerors

- Quoters shall submit a quote for all requirements listed in this Notice using the Deliverables Table above or something substantially similar. Partial quotes will not be considered. Incomplete pricing or pricing with omissions may not be considered for award.
- Quoters shall submit all assumptions in their quotation.
- Quoters are advised that additional terms and conditions submitted with their quotation that is in conflict of the terms and conditions of this solicitation may be deemed as technically unacceptable and may not be considered for award. All additional terms and conditions must be submitted with its quotation.

- Quoters shall submit all applicable terms and conditions in full text as attachments, appendix, or exhibits.
- All Quoters providing quotations must clearly state the overall cost to the Government.
- The Government reserves the right to award without dialogue. The Government does not intend to have dialogue to allow revision of the quotation. But the Government reserves the right to dialogue with Quoters should the Government determined it is necessary for quotation revisions prior to award.
- Quoters should ensure that their initial submission represents their best pricing and that all information is provided to determine technical acceptability. The Government will not research items to determine compatibility; all information regarding compatibility must be contained within the quotation.
- Questions about this public notice must be submitted to Bradley Hill by email at bradley.hill@fda.hhs.gov no later than 12:00 Noon Eastern Time (ET) on August 7, 2020. Phone calls will not be accepted.
- Quotes must be submitted to bradley.hill@fda.hhs.gov no later than 12:00 Noon Eastern Time (ET), on August 7, 2020. Phone calls will not be accepted.
- Quotes shall clearly be marked as response to FDA-20-SOL-1227159.

20. Award Basis

The FDA will evaluate quotes received in response to this Public Notice on a lowest price-technically-acceptable basis. A technically acceptable quote is one that offers to provide the FDA with the goods and services specified in this Statement of Work within the specified delivery schedule.

Failure to demonstrate meeting the requirements of this notice will result in a rating of technically unacceptable and will not be considered for award.