NIH NATIONAL CANCER INSTITUTE

Posting Date: 2/2/2022

Closing Date: February 4, 2022 11:30 a.m. ET

Reference Number: 22-014290

To: NCI Bid Board

From: Carolyn Bryant
NCI CCR P-ARC
bryantca@mail.nih.gov

Subject: NCI Bid Board Posting – Certification Testing Laboratory Services for GALV / RD114 Extended RCR (10 samples/assay or 1x10E8 cells) for The Surgery Branch.

The National Cancer Institute (NCI) The Surgery Branch (SB) Our efforts in accomplishing this objective are varied and include an increasing number of gene therapy clinical trials. Most of our current clinical approaches in this area involve the generation of cell/gene transfer therapies following lymphodepleting chemotherapy. These immunotherapy studies were initially focused on the treatment of patients with metastatic melanoma; however, recent characterization of genes encoding T-cell receptors (TCRs) that are capable of recognizing common epithelial antigens have allowed us to expand these approaches for the treatment of patients with common epithelial malignancies.

The primary objective of the testing is to assay for Gibbon Ape Leukemia (GALV) sequences using a quantitative PCR (qPCR) detection method, to assay for RD114 envelope sequences using the cell-based S+L- detection method; and to assay for presence of adventitious virus with a cell-based method utilizing Vero, MRC-5, and NIH-3T3 cells.

The National Cancer Institute, Surgery Branch plans to purchase certification testing laboratory services for RD114 samples/ assay from Indiana University Vector Production Facility. This is not a request for competitive quotations. However, if any interested party believes it can meet the attached requirements, it may submit a statement of capabilities. The capability statement must be in writing and must contain information and material in sufficient detail to allow NCI to determine is the party can fully meet this requirement. The capability statement must be received in the contracting office by 11:30 AM on February 14, 2022 ET. A determination by the Government not to compete this requirement based upon responses to this notice is solely within the discretion of the Government. Information received will be considered solely for the purpose of determining whether to conduct a competitive procurement.

Source Justification:
The professional services from Indiana University Gene Therapy Testing Laboratory (IU GTTL) is a well-established core laboratory within the Indiana University School of Medicine and the Department of Medical and Molecular Genetics and is dedicated to the development, production and testing of gene therapy technology. The IU GTTL offers a wide variety of routine and specialized assays important in safety testing and certifying both clinical and non-clinical grade vectors. Due to the patent rights the warranty will be voided if serviced by another vendor. The NCI sees this as a sole source acquisition since a previous award (HHSN261201800436P) was performed to this institution and further testing is required.

Attached Documents:
SF18
Statement of Work
52.204-24 Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment.
FAR Clause 52.213-4 Simplified Acquisitions Terms and Conditions (JAN 2014) is applicable and available in full text upon request

# REQUEST FOR QUOTATION
*(THIS IS NOT AN ORDER)*

THIS RFQ ☐ IS ☒ IS NOT A SMALL BUSINESS SET-ASIDE

PAGE 1 OF PAGES 1

| 1. REQUEST NUMBER | 2. DATE ISSUED | 3. REQUISITION/PURCHASE REQUEST NUMBER | 4. CERT. FOR NAT. DEF. UNDER BDSA REG. 2 AND/OR DMS REG. 1 | RATING |
|---|---|---|---|---|
| POTS 22-014290 | 2/4/2022 | POTS 22-014290 | | |

5a. ISSUED BY

6. DELIVER BY *(Date)*: 2/14/2022

5b. FOR INFORMATION CALL *(NO COLLECT CALLS)*

| NAME | TELEPHONE NUMBER | |
|---|---|---|
| | AREA CODE | NUMBER |
| Carolyn Bryant | 301 | 480-7186 |

7. DELIVERY ☐ FOB DESTINATION ☒ OTHER *(See Schedule)*

9. DESTINATION

a. NAME OF CONSIGNEE: Kaitlyn Wu 240-760-6652

8. TO:

| a. NAME | b. COMPANY | b. STREET ADDRESS |
|---|---|---|
| | Indiana Univ. Vector Production Facility | 10 Center Dr, Bldg 3 Rm 4W19 |

| c. STREET ADDRESS | c. CITY |
|---|---|
| 980 W. Walnut. R3-C602 | Bethesda |

| d. CITY | e. STATE | f. ZIP CODE | d. STATE | e. ZIP CODE |
|---|---|---|---|---|
| Indianapolis | IN | 46202 | MD | 20892 |

10. PLEASE FURNISH QUOTATIONS TO THE ISSUING OFFICE IN BLOCK 5a ON OR BEFORE CLOSE OF BUSINESS *(Date)*: 2/14/2022

IMPORTANT: This is a request for information and quotations furnished are not offers. If you are unable to quote, please so indicate on this form and return it to the address in Block 5a. This request does not commit the Government to pay any costs incurred in the preparation of the submission of this quotation or to contract for supplies or service. Supplies are of domestic origin unless otherwise indicated by quoter. Any representations and/or certifications attached to this Request for Quotation must be completed by the quoter.

11. SCHEDULE *(Include applicable Federal, State and local taxes)*

| ITEM NUMBER (a) | SUPPLIES/SERVICES (b) | QUANTITY (c) | UNIT (d) | UNIT PRICE (e) | AMOUNT (f) |
|---|---|---|---|---|---|
| 1 | Certification Testing Laboratory Services - GALV / RD114 Extended RCR (10 samples/assay or 1X10E8 cells)<br><br>Notice of Intent: If submitting capability statement, please e-mail only 1 copy of the technical capability statement to Carolyn Bryant bryantca@mail.nih.com<br><br>See attachment statement of work.<br>This will be awarded as a Firm-Priced Contract. | 1 | | | |

| 12. DISCOUNT FOR PROMPT PAYMENT | a. 10 CALENDAR DAYS (%) | b. 20 CALENDAR DAYS (%) | c. 30 CALENDAR DAYS (%) | d. CALENDAR DAYS NUMBER | d. CALENDAR DAYS PERCENTAGE |
|---|---|---|---|---|---|
| | | | 0.00 | | |

NOTE: Additional provisions and representations ☐ are ☐ are not attached.

| 13. NAME AND ADDRESS OF QUOTER | 14. SIGNATURE OF PERSON AUTHORIZED TO SIGN QUOTATION | 15. DATE OF QUOTATION |
|---|---|---|
| a. NAME OF QUOTER | | |
| b. STREET ADDRESS | 16. SIGNER | |
| | a. NAME *(Type or print)* | b. TELEPHONE AREA CODE |
| c. COUNTY | | |
| d. CITY / e. STATE / f. ZIP CODE | c. TITLE *(Type or print)* | NUMBER |

AUTHORIZED FOR LOCAL REPRODUCTION
Previous edition not usable

**STANDARD FORM 18 (REV. 6/1995)**
Prescribed by GSA-FAR (48 CFR) 53.215-1(a)

# STATEMENT OF WORK (SOW)

**<u>Instructions:</u> This document should be used for the acquisition of SERVICES. Instructions (and sample language) for completion are in red, and should be excluded from the completed document.**

## 1.0 TITLE

Replication Competent Retrovirus (RCR) Testing

## 2.0 BACKGROUND

One of the main objectives of the Surgery Branch of the National Cancer Institute is to conduct basic and translational laboratory and clinical research aimed at improving the management of patients with cancer.

Our efforts in accomplishing this objective are varied and include an increasing number of gene therapy clinical trials. Most of our current clinical approaches in this area involve the generation of cell/gene transfer therapies following lymphodepleting chemotherapy. These immunotherapy studies were initially focused on the treatment of patients with metastatic melanoma; however, recent characterization of genes encoding T-cell receptors (TCRs) that are capable of recognizing common epithelial antigens have allowed us to expand these approaches for the treatment of patients with common epithelial malignancies. These TCRs targeting specific tumor antigens and/or cytokines are introduced into PG13, a murine NIH 3T3 cell line, in the context of a packageable retroviral genome, and the selected cell clone is used to generate a master cell bank (MCB) that constitutively produces retroviral vector particles. The MCB is then fully characterized and tested for biosafety before being used to generate a clinical-grade retroviral vector supernatant. It is this vector that then serves as the vehicle for gene delivery into patient's immune cells *ex vivo*.

## 2.1 OBJECTIVE

The objectives of this testing are the following:

- to assay for Gibbon Ape Leukemia (GALV) sequences using a quantitative PCR (qPCR) detection method;
- to assay for RD114 envelope sequences using the cell-based S+L- detection method; and,
- to assay for presence of adventitious virus with a cell-based method utilizing Vero, MRC-5, and NIH-3T3 cells.

## 3.0 SCOPE

Active monitoring for evidence of RCR and adventitious viral contaminant infection in patients enrolled in gene therapy clinical trials using retroviral vectors is currently required by the FDA. These recommendations were originally submitted in a letter to Sponsors of INDs Using Retroviral Vectors, dated September 20, 1993 and alternative timepoints for monitoring were subsequently provided in the January 2020 Guidance for Industry entitled, "Testing of Retroviral Vector-Based Human Gene Therapy Products for Replication Competent Retrovirus During Product Manufacture and Patient Follow-up", which was based on data accumulated in ongoing gene therapy clinical trials using retroviral vectors. The RCR monitoring schedule recommended in the guidance for vector supernatant lots includes analysis of patient samples at the following time points: pre-treatment, 3-, 6-, and 12-months after treatment. If all post-treatment assays (i.e., 3-, 6-, and 12-month timepoints) are negative, then collection of the yearly follow-up samples will be discontinued for that individual, and yearly review of medical history will be sufficient for that individual. Additionally, the guidance recommends testing of end of production cells for RCR.

Finally, testing for the presence of adventitious virus that could be introduced during production of vector supernatant is described in ICH Topic Q5 A (R1): "Quality of Biotechnological Products: Viral Safety Evaluation of Biotechnology Productions Derived from Cell Lines of Human or Animal Origin" (October 1997). This testing is recommended for cell lines utilized in the production of vector supernatant.

Two methods are currently in use and recommended by the FDA for detecting evidence of RCR infection in patient peripheral blood lymphocyte specimens: 1) detection of RCR-specific antibodies; and 2) analysis of patient peripheral blood mononuclear cells by polymerase chain reaction (PCR) for RCR-specific DNA sequences. The choice of assay may depend on the mode of vector administration and the clinical indication. For example, it has been shown that direct administration of vector producer cells or repeat direct injection of a vector can result in vector-specific antibodies which do not correlate with the presence of RCR (Refs. 3-4). Therefore, in cases where vector or vector-producing cells are directly administered, a PCR assay may be preferable over serologic monitoring. Additional instances where monitoring of patients by PCR may be preferred over serologic monitoring, are those cases where the patients are immunocompromised to an extent that antibody production may be minimal or not at all.

The method currently in use and recommended by the FDA for detecting evidence of RCR infection in patient cell infusion product is co-culture with a permissive cell line in order to amplify any potential RCR present.

The method currently in use and recommended for testing for presence of adventitious viral contaminants is a cell-based method involving at least two passages of cells to observe for cytopathic changes at varying temperatures.

## 4.0 CONTRACT REQUIREMENTS/ AND PERSONNEL QUALIFICATIONS

**_In Vitro_ Detection of Retrovirus by PCR for the GALV Envelope**

- The objective of this study is to assay for Gibbon Ape Leukemia (GALV) sequences using a quantitative PCR (qPCR) detection method.
- The testing procedure, volumes, and durations are according to established SOPs at the IU GTTL.
- The method for detecting GALV uses a real time qPCR technique that employs a probe and primer set designed to detect GALV sequences. Adequacy of the amount of test article material analyzed is assessed by a second probe and primer set designed to detect human apolipoprotein B (ApoB) gene sequences.
- DNA is purified from the test and control samples and amplified. The amplified product is analyzed for GALV envelope sequences by a radiolabeled gel blot probe. The film of the gel is visually examined for a band of expected size. Photographic records are retained.
- Test sample is $10^6$ cells.
- Retention of representative samples is the responsibility of the Surgery Branch.
- Raw data pertaining to each report, a copy of the report, and records of the SOPs are maintained in the IU GTTL minimally 3 years after release to the Surgery Branch.
- The Surgery Branch will be provided a final study report that includes a summary of the assay and results.

**_In Vitro_ Detection of Retrovirus by S+L- for the RD114 Envelope**

- The objective of this study is to assay for RD114 envelope sequences using the cell-based S+L- detection method.
- The testing procedure, volumes, and durations are according to established SOPs at the IU GTTL.

- The method for detecting RD114 uses cell-based method in which the test sample is placed into culture with 293 cells and maintained in culture for three weeks to enhance the replication of any infectious retrovirus that may be present.
- Culture fluid is collected from the final passage, filtered and inoculated onto PG-4 cells. Each culture well of the PG-4 indicator cells are examined for foci at the time the indicator cells appear confluent. If present the foci are enumerated. All culture well observations are recorded.
- Test sample size is determined in consultation with IU GTTL.
- Retention of representative samples is the responsibility of the Surgery Branch.
- Raw data pertaining to each report, a copy of the report, and records of the SOPs are maintained in the IU GTTL minimally 3 years after release to the Surgery Branch.
- The Surgery Branch will be provided a final study report that includes a summary of the assay and results.

***In Vitro* Detection of Adventitious Viral Contaminants**

- The objective of this study is to assay for presence of adventitious virus with a cell-based method utilizing Vero, MRC-5, and NIH-3T3 cells.
- The testing procedure, volumes, and durations are according to established SOPs at the IU GTTL.
- The method for detecting the presence of adventitious virus involves using a cell culture technique in which Vero, MRC-5, and NIH-3T3 cells are inoculated with the test sample and appropriate controls and passaged for 14 days. All cultures are observed for cytopathic changes and evaluated for hemadsorption using guinea pig, chicken, and human type 'O' erythrocytes at temperatures of 2-8°C, 20-25°C, and 36-38°C.
- Tissue culture fluid from negative samples are inoculated onto fresh indicator cells and passaged 14 additional days. Cultures are observed for cytopathic changes and evaluated for hemadsorption using guinea pig, chicken, and human type 'O' erythrocytes at temperatures of 2-8°C, 20-25°C, and 36-38°C.
- Test sample size is determined in consultation with IU GTTL.
- Retention of representative samples is the responsibility of the Surgery Branch.
- Raw data pertaining to each report, a copy of the report, and records of the SOPs are maintained in the IU GTTL minimally 3 years after release to the Surgery Branch.
- The Surgery Branch will be provided a final study report that includes a summary of the assay and results.

## 5.0 TYPE OF ORDER

This is a Firm Fixed-Price Purchase Order.

## 6.0 PERIOD OF PERFORMANCE: N/A

## 7.0 PLACE OF PERFORMANCE

Indiana University Gene Therapy Testing Laboratory
980 West Walnut St., R3-C668
Indianapolis, IN 46202
Phone: (317) 274-0340 / Fax: (317) 278-3327

## 8.0 REPORT(S)/DELIVERABLES AND DELIVERY SCHEDULE

## STATEMENT OF WORK (SOW)

The deliverables shall consist of the RCR and adventitious viral contaminant testing results for peripheral blood lymphocytes and cell infusion specimens of patients treated on gene therapy protocols utilizing retroviral vectors and conducted by the Surgery Branch, which were obtained at specific time points as determined by the FDA ; and adventitious viral contaminant testing results for specimens of cells utilized in the production of retroviral vector supernatant manufactured by the Surgery Branch for patients enrolled in Surgery Branch gene therapy protocols.

The results will be delivered to Jennifer Pappas, MHS, Regulatory Affairs Manager, Clinical Monitoring Research Program (CMRP), Frederick National Laboratory for Cancer Research, Leidos Biomedical Research, Inc after completion of all required testing by IU GTTL.

### 9.0 PAYMENT

Payment shall be made _once_____. Payment authorization requires submission and approval of invoices to the COR and NIH OFM, in accordance with the attached payment provisions listed below:

The following clause is applicable to all Purchase Orders, Task or Delivery Orders, and Blanket Purchase Agreement (BPA) Calls: PROMPT PAYMENT (JUL 2013) FAR 52.232-25. Highlights of this clause and NIH implementation requirements follow:

I INVOICE REQUIREMENTS

A. An invoice is the Contractor's bill or written request for payment under the contract for supplies delivered or services performed. A proper invoice is an "Original" which must include the items listed in subdivisions 1 through 12, below, in addition to the requirements of FAR 32.9. If the invoice does not comply with these requirements, the Contractor will be notified of the defect within 7 days after the date the designated billing office received the invoice (3 days for meat, meat food products, or fish, and 5 days for perishable agricultural commodities, dairy products, edible fats or oils) with a statement of the reasons why it is not a proper invoice. (See exceptions under II., below.) Untimely notification will be taken into account in the computation of any interest penalty owed the Contractor.

1. Vendor/Contractor: Name, Address, Point of Contact for the invoice (Name, title, telephone number, e-mail and mailing address of point of contact).
2. Remit-to address (Name and complete mailing address to send payment).
3. Remittance name must match exactly with name on original order/contract. If the Remittance name differs from the Legal Business Name, then both names must appear on the invoice.
4. Invoice date.
5. Unique invoice #s for all invoices per vendor regardless of site.
6. NBS document number formats must be included for awards created in the NBS: Contract Number; Purchase Order Number; Task or Delivery Order Number and Source Award Number (e.g., Indefinite Delivery Contract number; General Services Administration number); or, BPA Call Number and BPA Parent Award Number.
7. Data Universal Numbering System (DUNS) or DUNS + 4 as registered in the Central Contractor Registration (CCR).
8. Federal Taxpayer Identification Number (TIN). In those exceptional cases where a contractor does not have a DUNS number or TIN, a Vendor Identification Number (VIN)

must be referenced on the invoice. The VIN is the number that appears after the contractor's name on the face page of the award document.

9. Identify that payment is to be made using a three-way match.
10. Description of supplies/services that match the description on the award, by line billed.*
11. Freight or delivery charge must be billed as shown on the award. If it is included in the item price do not bill it separately. If identified in the award as a separate line item, it must be billed separately.
12. Quantity, Unit of Measure, Unit Price, Extended Price of supplies delivered or services performed, as applicable, and that match the line items specified in the award.*

* NOTE: If your invoice must differ from the line items on the award, please contact the Contracting Officer before submitting the invoice. A modification to the order or contract may be needed before the invoice can be submitted and paid.

B. Shipping costs will be reimbursed only if authorized by the Contract/Purchase Order. If authorized, shipping costs must be itemized. Where shipping costs exceed $100, the invoice must be supported by a bill of lading or a paid carrier's receipt.

C. Mail an original and 1 copy of the itemized invoice to:

National Institutes of Health
Office of Financial Management, Commercial Accounts
2115 East Jefferson Street, Room 4B-432, MSC 8500
Bethesda, MD 20892-8500

For inquiries regarding payment call: (301) 496-6088

In order to facilitate the prompt payment of invoices, it is recommended that the vendor submit a photocopy of the invoice to the "Consignee" designated for the acquisition in blocks 6A – 6E of the face page of the Order/Award document.

II. INVOICE PAYMENT

A. Except as indicated in paragraph B., below, the due date for making invoice payments by the designated payment office shall be the later of the following two events:

1. The 30th day after the designated billing office has received a proper invoice.
2. The 30th day after Government acceptance of supplies delivered or services performed.

B. The due date for making invoice payments for meat and meat food products, perishable agricultural commodities, dairy products, and edible fats or oils, shall be in accordance with the Prompt Payment Act, as amended.

III. INTEREST PENALTIES

A. An interest penalty shall be paid automatically, if payment is not made by the due date and the conditions listed below are met, if applicable.

1. A proper invoice was received by the designated billing office.
2. A receiving report or other Government documentation authorizing payment was processed and there was no disagreement over quantity, quality, or contractor compliance with a term or condition.
3. In the case of a final invoice for any balance of funds due the contractor for supplies delivered or services performed, the amount was not subject to further settlement actions between the Government and the Contractor.

B. Determination of interest and penalties due will be made in accordance with the provisions of the Prompt Payment Act, as amended, the Contract Disputes Act, and regulations issued by the Office of Management and Budget.

IV. PROVIDING ACCELERATED PAYMENT TO SMALL BUSINESS SUBCONTRACTORS, FAR 52.232-40 (DEC 2013)

a) Upon receipt of accelerated payments from the Government, the Contractor shall make accelerated payments to its small business subcontractors under this contract, to the maximum extent practicable and prior to when such payment is otherwise required under the applicable contract or subcontract, after receipt of a proper invoice and all other required documentation from the small business subcontractor.
b) The acceleration of payments under this clause does not provide any new rights under the prompt Payment Act.

Include the substance of this clause, include this paragraph c, in all subcontracts with small business concerns, including subcontracts with small business concerns for the acquisition of commercial items.

**52.204-24 Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment.**

As prescribed in 4.2105(a), insert the following provision:

REPRESENTATION REGARDING CERTAIN TELECOMMUNICATIONS AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT (AUG 2019)

(a) Definitions. As used in this provision—

Covered telecommunications equipment or services, Critical technology, and Substantial or essential component have the meanings provided in clause 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.

(b) Prohibition. Section 889(a)(1)(A) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232) prohibits the head of an executive agency on or after August 13, 2019, from procuring or obtaining, or extending or renewing a contract to procure or obtain, any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. Contractors are not prohibited from providing—

(1) A service that connects to the facilities of a third-party, such as backhaul, roaming, or interconnection arrangements; or

(2) Telecommunications equipment that cannot route or redirect user data traffic or permit visibility into any user data or packets that such equipment transmits or otherwise handles.

(c) Representation. The Offeror represents that—

It [ ] will, [ ] will not provide covered telecommunications equipment or services to the Government in the performance of any contract, subcontract or other contractual instrument resulting from this solicitation.

(d) Disclosures. If the Offeror has responded affirmatively to the representation in paragraph (c) of this provision, the Offeror shall provide the following information as part of the offer—

(1) All covered telecommunications equipment and services offered (include brand; model number, such as original equipment manufacturer (OEM) number, manufacturer part number, or wholesaler number; and item description, as applicable);

(2) Explanation of the proposed use of covered telecommunications equipment and services and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (b) of this provision;

(3) For services, the entity providing the covered telecommunications services (include entity name, unique entity identifier, and Commercial and Government Entity (CAGE) code, if known); and

(4) For equipment, the entity that produced the covered telecommunications equipment (include entity name, unique entity identifier, CAGE code, and whether the entity was the OEM or a distributor, if known).

(End of provision)

**52.213-4 Terms and Conditions-Simplified Acquisitions (Other Than Commercial Items).**

As prescribed in 13.302-5(d), insert the following clause:

TERMS AND CONDITIONS-SIMPLIFIED ACQUISITIONS (OTHER THAN COMMERCIAL ITEMS) (AUG 2020)

(a) The Contractor shall comply with the following Federal Acquisition Regulation (FAR) clauses that are incorporated by reference:

(1) The clauses listed below implement provisions of law or Executive order:

(i) 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)).

(ii) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (JUL 2018) (Section 1634 of Pub. L. 115-91).

(iii) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (AUG 2020) (Section 889(a)(1)(A) of Pub. L. 115-232).

(iv) 52.222-3, Convict Labor (JUN 2003) (E.O.11755).

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

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

(vii) 52.225-13, Restrictions on Certain Foreign Purchases (Jun 2008) (E.O.s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).

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

(ix) 52.233-4, Applicable Law for Breach of Contract Claim (OCT 2004) (Pub.L.108-77, 108-78 (19 U.S.C. 3805 note)).

(2) Listed below are additional clauses that apply:

(i) 52.232-1, Payments (APR 1984).

(ii) 52.232-8, Discounts for Prompt Payment (FEB 2002).

(iii) 52.232-11, Extras (APR 1984).

(iv) 52.232-25, Prompt Payment (JAN 2017) .

(v) 52.232-39, Unenforceability of Unauthorized Obligations (JUN 2013).

(vi) 52.232-40, Providing Accelerated Payments to Small Business Subcontractors (DEC 2013).

(vii) 52.233-1, Disputes (MAY 2014).

(viii) 52.244-6, Subcontracts for Commercial Items (AUG 2020).

(ix) 52.253-1, Computer Generated Forms (JAN 1991).

(b) The Contractor shall comply with the following FAR clauses, incorporated by reference, unless the circumstances do not apply:

(1) The clauses listed below implement provisions of law or Executive order:

(i) 52.204-10, Reporting Executive Compensation and First-Tier Subcontract Awards (JUN 2020)(Pub. L. 109-282) (31 U.S.C. 6101 note) (Applies to contracts valued at or above the threshold specified in FAR 4.1403(a) on the date of award of this contract).

(ii) 52.222-19, Child Labor-Cooperation with Authorities and Remedies (JAN 2020) (E.O.13126) (Applies to contracts for supplies exceeding the micro-purchase threshold, as defined in FAR 2.101 on the date of award of this contract).

(iii) for Materials, Supplies, Articles, and Equipment., Contracts for Materials, Supplies, Articles, and Equipment (JUN 2020) (41 U.S.C.chapter 65) (Applies to supply contracts over the threshold specified in FAR 22.602 on the date of award of this contract, in the United States, Puerto Rico, or the U.S. Virgin Islands).

(iv) 52.222-35, Equal Opportunity for Veterans (JUN 2020) (38 U.S.C.4212) (Applies to contracts valued at or above the threshold specified in FAR 22.1303(a) on the date of award of this contract).

(v) 52.222-36, Equal Employment for Workers with Disabilities (JUN 2020) (29 U.S.C.793) (Applies to contracts over the threshold specified in FAR 22.1408(a) on the date of award of this contract, unless the work is to be performed outside the United States by employees recruited outside the United States). (For purposes of this clause, "United States" includes the 50 States, the District of Columbia, Puerto Rico, the Northern Mariana Islands, American Samoa, Guam, the U.S. Virgin Islands, and Wake Island.)

(vi) 52.222-37, Employment Reports on Veterans (JUN 2020) (38 U.S.C.4212) (Applies to contracts valued at or above the threshold specified in FAR 22.1303(a) on the date of award of this contract).

(vii) 52.222-41, Service Contract Labor Standards (AUG 2018) (41 U.S.C.chapter 67) (Applies to service contracts over $2,500 that are subject to the Service Contract Labor Standards statute and will be performed in the United States, District of Columbia, Puerto Rico, the Northern Mariana Islands, American Samoa, Guam, the U.S. Virgin Islands, Johnston Island, Wake Island, or the outer Continental Shelf).

(viii)(viii)

(A) 52.222-50, Combating Trafficking in Persons (JAN 2019) (22 U.S.C. chapter78 and E.O 13627) (Applies to all solicitations and contracts).

(B) Alternate I (MAR 2015) (Applies if the Contracting Officer has filled in the following information with regard to applicable directives or notices: Document title(s), source for obtaining document(s), and contract performance location outside the United States to which the document applies).

(ix) 52.222-55, Minimum Wages Under Executive Order 13658 (DEC 2015) (Applies when 52.222-6 or 52.222-41 are in the contract and performance in whole or in part is in the United States (the 50 States and the District of Columbia)).

(x) 52.222-62, Paid Sick Leave Under Executive Order 13706 (J*an* 2017) (E.O. 13706) (Applies when 52.222-6 or 52.222-41 are in the contract and performance in whole or in part is in the United States (the 50 States and the District of Columbia.))

(xi) 52.223-5, Pollution Prevention and Right-to-Know Information (MAY 2011) (E.O. 13423) (Applies to services performed on Federal facilities).

(xii) 52.223-11, Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons (JUN 2016) (E.O. 13693)(applies to contracts for products as prescribed at FAR 23.804(a)(1)).

(xiii) 52.223-12, Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners (JUN 2016) (E.O. 13693) (Applies to maintenance, service, repair, or disposal of refrigeration equipment and air conditioners).

(xiv) 52.223-15, Energy Efficiency in Energy-Consuming Products (DEC 2007) (42 U.S.C. 8259b) (Unless exempt pursuant to 23.204, applies to contracts when energy-consuming products listed in the ENERGY STAR® Program or Federal Energy Management Program (FEMP)) will be-

(A) Delivered;

(B) Acquired by the Contractor for use in performing services at a Federally-controlled facility;

(C) Furnished by the Contractor for use by the Government; or

(D) Specified in the design of a building or work, or incorporated during its construction, renovation, or maintenance).

(xv) 52.223-20, Aerosols (JUN 2016) (E.O. 13693) (Applies to contracts for products that may contain high global warming potential hydrofluorocarbons as a propellant or as a solvent; or contracts for maintenance or repair of electronic or mechanical devices).

(xvi) 52.223-21, Foams (JUN 2016) (E.O. 13693) (Applies to contracts for products that may contain high global warming potential hydrofluorocarbons or refrigerant blends containing hydrofluorocarbons as a foam blowing agent; or contracts for construction of buildings or facilities.

(xvii) 52.225-1, Buy American-Supplies (MAY 2014) (41 U.S.C.chapter 67) (Applies to contracts for supplies, and to contracts for services involving the furnishing of supplies, for use in the United States or its outlying areas, if the value of the supply contract or supply portion of a service contract exceeds the micro-purchase threshold, as defined in FAR 2.101 on the date of award of this contract, and the acquisition-

(A) Is set aside for small business concerns; or

(B) Cannot be set aside for small business concerns (see 19.502-2), and does not exceed $25,000).

(xviii) Excess Food Donation to Nonprofit Organizations., Promoting Excess Food Donation to Nonprofit Organizations (JUN 2020) (42 U.S.C. 1792) (Applies to contracts greater than the threshold specified in FAR 26.404 on the date of award of this contract, that provide for the provision, the service, or the sale of food in the United States).

(xix) 52.232-33, Payment by Electronic Funds Transfer-System for Award Management (OCT 2013)(Applies when the payment will be made by electronic funds transfer (EFT) and the payment office uses the System for Award Management (SAM) as its source of EFT information).

(xx) 52.232-34, Payment by Electronic Funds Transfer-Other than System for Award Management (JUL 2013) (Applies when the payment will be made by EFT and the payment office does not use the SAM database as its source of EFT information).

(xxi) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (FEB 2006) (46 U.S.C.App.1241) (Applies to supplies transported by ocean vessels (except for the types of subcontracts listed at 47.504(d)).

(2) Listed below are additional clauses that may apply:

(i) 52.204-21, Basic Safeguarding of Covered Contractor Information Systems (JUN 2016) (Applies to contracts when the contractor or a subcontractor at any tier may have Federal contract information residing in or transiting through its information system.

(ii) 52.209-6, Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment (JUN 2020) (Applies to contracts over the threshold specified in FAR 9.405-2(b) on the date of award of this contract).

(iii) 52.211-17, Delivery of Excess Quantities (*Sept* 1989) (Applies to fixed-price supplies).

(iv) 52.247-29, F.o.b. Origin (FEB 2006) (Applies to supplies if delivery is f.o.b. origin).

(v) 52.247-34, F.o.b. Destination (NOV 1991) (Applies to supplies if delivery is f.o.b. destination).

(c) *FAR 52.252-2, Clauses Incorporated by Reference (Feb 1998)*. This contract 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/these address(es):

_____

_____

*[Insert one or more Internet addresses]*

(d) *Inspection/Acceptance*. The Contractor shall tender for acceptance only those items that conform to the requirements of this contract. The Government reserves the right to inspect or test any supplies or services that have been tendered for acceptance. The Government may require repair or replacement of nonconforming supplies or reperformance of nonconforming services at no increase in contract price. The Government must exercise its postacceptance rights-

(1) Within a reasonable period of time after the defect was discovered or should have been discovered; and

(2) Before any substantial change occurs in the condition of the item, unless the change is due to the defect in the item.

(e) *Excusable delays*. The Contractor shall be liable for default unless nonperformance is caused by an occurrence beyond the reasonable control of the Contractor and without its fault or negligence, such as acts of God or the public enemy, acts of the Government in either its sovereign or contractual capacity, fires, floods, epidemics, quarantine restrictions, strikes, unusually severe weather, and delays of common carriers. The Contractor shall notify the Contracting Officer in writing as soon as it is reasonably possible after the commencement of any excusable delay, setting forth the full particulars in connection therewith, shall remedy such occurrence with all reasonable dispatch, and shall promptly give written notice to the Contracting Officer of the cessation of such occurrence.

(f) *Termination for the Government's convenience*. The Government reserves the right to terminate this contract, or any part hereof, for its sole convenience. In the event of such termination, the Contractor shall immediately stop all work hereunder and shall immediately cause any and all of its suppliers and subcontractors to cease work. Subject to the terms of this contract, the Contractor shall be paid a percentage of the contract price reflecting the percentage of the work performed prior to the notice of termination, plus reasonable charges that the Contractor can demonstrate to the satisfaction of the Government, using its standard record keeping system, have resulted from the termination. The Contractor shall not be required to comply with the cost accounting standards or contract cost principles for this purpose. This paragraph does not give the Government any right to audit the Contractor’s records. The Contractor shall not be paid for any work performed or costs incurred that reasonably could have been avoided.

(g) *Termination for cause*. The Government may terminate this contract, or any part hereof, for cause in the event of any default by the Contractor, or if the Contractor fails to comply with any contract terms and conditions, or fails to provide the Government, upon request, with adequate assurances of future performance. In the event of termination for cause, the Government shall not be liable to the Contractor for any amount for supplies or services not accepted, and the Contractor shall be liable to the Government for any and all rights and remedies provided by law. If it is determined that the Government improperly terminated this contract for default, such termination shall be deemed a termination for convenience.

(h) *Warranty*. The Contractor warrants and implies that the items delivered hereunder are merchantable and fit for use for the particular purpose described in this contract.

(End of clause)