

Amendment of Solicitation

Date of Issuance: 4/1/2020

Solicitation No. 3400001681

Requisition No. 3400020750

Amendment No. 2

Hour and date specified for receipt of offers is changed: ☐ No ☒ Yes, to: 4/21/2020 3:00 PM CST

Pursuant to OAC 260:115-7-30(d), this document shall serve as official notice of amendment to the solicitation identified above. Such notice is being provided to all suppliers to which the original solicitation was sent.

Suppliers submitting bids or quotations shall acknowledge receipt of this solicitation amendment prior to the hour and date specified in the solicitation as follows:

- (1) Sign and return a copy of this amendment with the solicitation response being submitted; or,
- (2) If the supplier has already submitted a response, this acknowledgement must be signed and returned prior to the solicitation deadline. All amendment acknowledgements submitted separately shall have the solicitation number and bid opening date printed clearly on the front of the envelope.

ISSUED BY and RETURN TO:

U.S. Postal Delivery:

Richard Williams
Contracting Officer

405 - 522 - 1040
Phone Number

, OK -

or

Personal or Common Carrier Delivery:

Richard.Williams@omes.ok.gov
E-Mail Address

,OK -

Description of Amendment:

a. This is to incorporate the following:

Below are changes to the specifications:

E.2. Submissions/Copies

~~E.2.1. Supplier is to submit TWO (2) complete copies of their response with ONE (1) copy on TWO (2) separate USB/Flash Drives which includes the completed proposal, including the scanned images of the OMES signed forms. USB/Flash Drives must be an unprotected document.~~

~~E.2.2. Faxed or emailed responses will not be accepted. Original hard copies are not required or preferred. This overrides hard copy submittal requirements of A.2.4. PDF is an acceptable format for solicitation responses. This overrides requirements of A.2.4~~

E.2.1. Bids are to be emailed to Richard.Williams@omes.ok.gov

E.2.1.1. Emails must contain solicitation number and the completed proposal, including the scanned images of the OMES signed forms.

E.2.1.2. Contracting officer will respond to bid email with a received receipt showing that we have received the bid.

E.2.1.2.1. If the vendor does not receive the received email reply, please contact the contracting officer via email stating that you sent in your bid.

E.2.2. This overrides submittal requirements of A.2.2. PDF is an acceptable format for solicitation responses. This overrides requirements of A.2.4

E.3. Bid Deliverables

~~E.3.1. Bids should be tabbed by section and clearly marked as Original or Copy.~~

~~E.3.2. Note: Bid deliverables are to be submitted in electronic copy on flash/thumb drive machine-readable format~~

E.3.1. Only one bid needs to be submitted but bidder may need to send multiple emails if the files are too big.

E.3.2. Each file should be labeled.

Below are the answers to all questions received:

Question 1: Is it allowable for the Owner / Partner of an existing OMMA Licensed Lab to also be the QA Lab, As long as the QA Lab has a separate facility, Instrumentation for performing the test and separate personnel running the test, Separate bookkeeping, etc. Only potential Ownership / Partnership interest in the QA Lab. And still operate the existing Licensed Cannabis Testing Lab?

Answer: The solicitation makes it clear that the purpose is to “engage an **independent** cannabis testing laboratory” to provide quality assurance and oversight of the other licensed testing laboratories in the State of Oklahoma. State statute, specifically 63 O.S. § 427.17(M), requires licensed laboratories to “establish policies to prevent the existence of or appearance of undue commercial, financial or other influences that may diminish the competency, impartiality and integrity of the testing processes or results of the laboratory, or that may diminish public confidence in the competency, impartiality and integrity of the testing processes or results of the laboratory.” This law also specifically prohibits employees, owners or agents of a medical marijuana testing laboratory who participate in any aspect of the analysis and results of a sample from “improperly benefiting from any ongoing financial, employment, personal or business relationship with the medical marijuana business that provided the sample.”

Question 2: If the answer to Question 1 is that it is not allowed is it acceptable to have an immediate family member / members be awarded the QA Lab Contract as long as there is no direct ownership to the current business?

Answer: No. The solicitation makes it clear that the purpose is to “engage an **independent** cannabis testing laboratory” to provide quality assurance and oversight of the other licensed testing laboratories in the State of Oklahoma. State statute, specifically 63 O.S. § 427.17(M), requires licensed laboratories to “establish policies to prevent the existence of or appearance of undue commercial, financial or other influences that may diminish the competency, impartiality and integrity of the testing processes or results of the laboratory, or that may diminish public confidence in the competency, impartiality and integrity of the testing processes or results of the laboratory.” This law also specifically prohibits employees, owners or agents of a medical marijuana testing laboratory who participate in any aspect of the analysis and results of a sample from “improperly benefiting from any ongoing financial, employment, **personal** or business relationship with the medical marijuana business that provided the sample.”

Question 3: Is it allowable for the QA Lab Owner / Partners to be Licensed by OMMA as a Cannabis Research Lab in addition to being the QA Lab?

Answer: Oklahoma law does not prohibit a testing laboratory from also obtaining a medical marijuana research license; however, any research conducted by the quality assurance lab would be subject to the terms and conditions of the statewide contract, including any terms regarding ownership of data, intellectual property, and use of equipment. Findings from research as the quality assurance lab may publishable in collaboration with OSDH.

Question 4: Related to Worker’s Comp insurance while we would fully carry Worker’s Comp insurance it would typically not be in place prior to being award the QA Lab Contract and forming the proper corporation. How would that need to be addressed as it appears we have to be exempt or have the insurance in place at the time of submitting the proposal? The same for the Sales Tax permit and registration with the Secretary of State for the registered business name.

Answer: The State must be able to verify Supplier compliance with Oklahoma law related to Worker’s Comp insurance, Sales Tax permit, and registration with the Secretary of State’s office prior to finalizing a contract.

Question 5: Also related to the date shown below from the RFP is the termination date to be June 30th 2021 rather than 2020?

Answer: The end date of 6/30/2020 anticipates the contract will be awarded prior to the end of the current state fiscal year and to allow the bulk of the agreement to operate concurrently with the state fiscal year. Oklahoma law prohibits state agencies from contracting for a period of more than one (1) year at a time. In the event the contract is not awarded prior to 6/30/2020, then the end date of the initial period would be 6/30/2021.

Question 6: We particularly wanted more details about the PT program, mainly the types of matrices to perform PT testing on – We assume flower and concentrate, but what about any other general products – edibles, etc.

Answer: The focus will be on flower and concentrate. As part of C.8.1.1.4, the QA Laboratory may be required to establish proficiency testing for analytes in which the matrix poses specific analytical challenges not known at this time. Section C.4.3 addresses unanticipated work not currently envisioned.

Question 7: Also what would be the number of participating labs for the PT program (assume the currently licensed labs would do this 3 times a year).

Answer: It is anticipated there will be between 12 and 20 testing laboratories operating in the state. However, state law does not limit the number of licenses that may be issued to testing laboratories.

Question 10: Federal law still treats marijuana as a controlled substance. Though this bid offering is not directly involved with the marijuana industry, it involves providing services to businesses operating under Oklahoma state marijuana laws and accordingly may be in violation of federal law and thus subject to prosecution:

Question 10A: What assurances can be provided to protect the vendor that will be participating in the collection, transportation and testing of marijuana?

Answer: Oklahoma law expressly authorizes and legalizes the services to be provided under this solicitation. OSDH cannot speak or provide assurances on behalf of the Federal Government. Please seek your own counsel regarding this question.

Question 10B: Has there been any discussions with federal authorities regarding the legality of the state to engage in this type of contract and the effects on vendors who will be executing the contract?

Answer: OSDH has not engaged in communications with the Federal Government regarding this solicitation.

Question 11: (page 13, B.3.1) Please confirm termination date as it states “This Contract will begin on the Date of Award and terminate on June 30, 2020.”

Answer: See question #5

Question 12: (page 16, B.13.1) – Will there be a grace period to come into compliance with VPAT and Oklahoma Information Technology Accessibility Standards?

Answer: No, please refer to the information contained on the State of Oklahoma’s Information and Communication Technology Accessibility Standards website which can be accessed via the following link <https://omes.ok.gov/services/information-services/accessibility-standards>. In addition the OSDH is currently utilizing the WCAG (web content accessibility guidelines) 2.0 AA

Question 13: (page 19, C.5.1.1) – Will there be a grace period to come into compliance with HIPPA requirements? Also, please confirm that HIPPA requirements are required for analytical laboratories that do not handle personal health information or patient data.

Answer: OSDH is a hybrid entity under HIPAA, which means that not all of the divisions within OSDH are subject to HIPAA. The Oklahoma Medical Marijuana Authority within OSDH is not a covered entity under HIPAA. However, OMMA and its contractual agents, including the quality assurance lab, would be required under 63 O.S. § 427.7(C) to keep all records regarding medical marijuana patient and caregiver licensees confidential.

Question 14: (page 19, C.6.2) Can the vendor provide the information requested in C.6.2 after the contract is awarded and cannabis testing is in progress?

- C.6.2.1. Reliability: Average time between unscheduled maintenance/repairs
- C.6.2.2. Accuracy: Proficiency Test results, including Standard Deviation Index
- C.6.2.3. Precision: Within-run and between-run coefficients of variation
- C.6.2.4. Throughput: Samples per day.
- C.6.2.5. The average turnaround time for completion of testing for each of the required analytes.

Answer: This information will be used to evaluate the bid. If the bidder is unable to provide the information they should indicate this in their response.

Question 15: (page 19, C.6.5.3) - Please confirm the window of time to be ISO 17025 accredited to specific tests following award of contract.

Answer: C.6.1 States the Quality Assurance Laboratory must meet the requirements to obtain a Testing Laboratory License as defined in OAC 310:681-8. Per this rule ISO 17025 accreditation is required for a laboratory to apply for a license or license renewal after January 1, 2020. Accreditation status will be used to evaluate the bid.

Question 16: (page 20, C.9.1.1.3) Please define "bias calculation".

Answer: The percentage and actual difference between the QA laboratory's and testing laboratory's results.

Question 17: (page 20, C.9.1.1.3) Will the state accept test results reported to OMMA with a longer turnaround time than one week? Some microbiology tests require more than 5 days to perform the test.

Answer: OMMA is not specifying a turnaround time for any analyte. The requirement in this section is that when testing is complete, the results are sent to OMMA within 1 week.

Question 18: (page 20, C.9.1.1.5) - Please define "LQC" as it states "Analyze LQC samples from testing laboratories."

Answer: Laboratory Quality Control.

Question 19: (page 21, C.10.1.4) - Please define "OMMA Seed to Sale system".

Answer: The seed-to-sale system, or "Inventory Tracking system" is defined in OAC 310:681-1-4 to mean "a required tracking system that accounts for the entire life span of medical marijuana, from either the seed or immature plant stage until the medical marijuana or medical marijuana product is consumed, used, disposed of or otherwise destroyed." State statute, specifically 63 O.S. § 427.13 requires all licensed business to utilize a seed-to-sale tracking system. 63 O.S. § 427.17(N)(8) specifically requires laboratories to utilize seed-to-sale tracking systems "to ensure all test batches or samples containing medical marijuana, medical marijuana concentrate or medical marijuana products are identified and tracked" and requires reporting through this system of any test results.

Question 20: (page 25, H.1.1) - Please define "water activity".

Answer: Water activity is defined as the energy status of water in a system, and represents the relative chemical potential energy of water in a sample.

Question 21: (page 25, H.1.1) - Please define "moisture content".

Answer: Moisture content is defined as the amount of water content in a sample.

Question 22: (page 25, H.1.1) - In trying to fill out our pricing grid information we are curious as to how the State would like us to handle the Year 1 pricing estimates when the Contract Period as stated in B.3.1 states that the Contract will begin on "Date of award and terminate on June 30 2020." Given that this total time period from Date of Award to Contract termination may only be a month, we were hoping the State may be able to provide some guidance as to what they may want to see when we explain pricing in our grid on H.1.1.

Answer: Each potential Supplier has an estimate of the amount of time required to have their proposed solution fully functioning, i.e. three (3) month, six (6) month, or some other period of time. Therefore the Year 1 pricing should be calculated from the date the proposed solution is fully functioning to June 30, 2020.

Question 23 How much will the state reimburse per test run by the lab?

Answer: The amount stated in the Contract Expense Cap is the total budget allocated by the OSDH to this project. The cost per test is to be proposed by the responding bidder (s). Cost, including per test pricing, is an evaluation criteria to be used in the selection of the awarded Supplier.

Question 24: Will the lab also be allowed to test commercial products, or will it be limited to supervising work only?

Answer: Refer to Section C.10.1.6: Commit all equipment to ONLY run testing for the OSDH OMMA. There can be no cross utilization of equipment for other lab purposes. State statute, specifically 63 O.S. § 427.17(B), specifically prohibits the quality assurance lab in contract with OSDH "from conducting any other commercial medical marijuana testing in this state."

b. All other terms and conditions remain unchanged.

Supplier Company Name (**PRINT**)

Date

Authorized Representative Name (**PRINT**)

Title

Authorized Representative Signature