

MARTIN O'MALLEY Governor ANTHONY BROWN Lieutenant Governor T. ELOISE FOSTER
Secretary

DAVID C. ROMANS
Deputy Secretary

Amendment #4 to Invitation for Bids (IFB), Project # F10B9200023 Forensic Toxicology Drug Testing Laboratory (FTDTL) May 15, 2009

Ladies/Gentlemen:

This Amendment #4 is being issued to change, add or delete certain information contained in the above named IFB. Specific parts of the IFB have been amended and the IFB changes are detailed below. The new language has been **double underlined and marked in bold** and deleted language has been marked with a strikeout (ex. strike out). These markings will help you more easily identify what has changed.

1. Change the Key Information Summary Sheet as follows:,

Closing Date/Time: Thursday Wednesday, May 6th 13th 19th 21st, 2009, 2:00 PM (Local Time)

Bid Opening Date/Time: Thursday Wednesday, May 6th 13th 19th 21st, 2009, 3:00 PM (Local Time) Room 164A–45 Calvert Street, Annapolis, MD 21401

2. Change IFB Section 1.8 to read:

An unbound original, plus two copies and an electronic CD version of the paper submission of the Bid must be received by the Procurement Officer, at the address listed in Section 1.5A, no later than May 6th, 13th 19th 21st 2009, 2:00 PM (Local Time) in order to be considered. Requests for extension of this date or time shall not be granted. Bidders mailing Bids should allow sufficient mail delivery time to ensure timely receipt by the Procurement Officer. Except as provided in COMAR 21.05.02.10, Bids received by the Procurement Officer after the closing time and date will not be considered. **Bids delivered by email or facsimile shall not be considered.**

Bids will be opened May 6th, 13th 19th 21st 2009, at 3:00 PM (Local Time), in Room 164A, 45 Calvert Street, Annapolis Maryland in accordance with the provisions of

COMAR 21.05.02.11B. Bids will be made available for public inspection at or within a reasonable time after Bid opening. Any material deemed confidential or proprietary by the Bidder must be clearly marked and shall be readily separable from the Bid to facilitate public inspection of the non-confidential portion of the Bid.

3. Change/add IFB Section 2.2.1 to read:

Laboratory and Testing Requirements: The laboratory shall be SAMHSA certified and adhere to the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Attachment K), as well as future revisions thereof. The laboratory shall maintain certification from SAMHSA throughout the duration of this Contract. Bidders shall submit copies of current SAMHSA certification with the Bid.

<u>Additionally, the Contractor shall be responsible for providing laboratory services in accordance with all applicable licensure, certification and accreditation standards of:</u>

- a. The State of Maryland, Department of Health & Mental Hygiene, Office of Health Care Quality
- b. Clinical Laboratory Improvements Act of 1988 (CLIA)
- c. All applicable Federal licenses and requirements

<u>The Contractor's laboratory must provide documentation to the Contract Manager, prior to the issuance of the Notice To Proceed (NTP), of the following current certifications held in the Contractor's name:</u>

- a. <u>Medical Laboratory Permit issued by the State of Maryland, Department of Health & Mental Hygiene, Office of Health Care Quality; and</u>
- b. **CLIA Certification**

Maryland law requires all laboratories (in State and out-of-State) to hold a permit issued by the Maryland Department of Health & Mental Hygiene, Office of Health Care Quality. Laboratories must be in compliance with all applicable Federal, State and local standards for the locality in which the laboratory is located.

<u>Laboratories must maintain CLIA certification for all clinical laboratory services</u> <u>performed on behalf of the State.</u> <u>If the Contractor's laboratory is located outside</u> <u>of the State of Maryland, the Contractor's CLIA Certification from its home state</u> <u>shall be submitted for requirement (b) as listed above. If the Contractor's laboratory is located within Maryland, a CLIA Certification issued by the State of Maryland is required.</u>

The Laboratory shall maintain all required permits and certifications throughout the duration of this Contract.

The CLIA application can be found on the website www.cms.hhs.gov/clia. For information pertaining to the permit process for the State of Maryland, you may

contact, the Coordinator for Laboratory Licensing & Surveying Office of Health Care Quality, sarahbennett@dhmh.state.md.us.

4. Change/add IFB Section 2.2.2 to read:

Reporting Requirements: The FTDTL Contractor shall fax copies of all lab reports to the Contract Manager within two business days of receipt of the specimen from the Collection Contractor. The two-day limit may be extended on a case-by-case basis, and for unusual circumstances, at the discretion of the MRO and/or the Contract Manager. The lab reports must reflect the results of all tests conducted by the laboratory, including tests for those samples that screen positive but do not confirm at the above-specified cut-off levels during the GC/MS process. All confirmed test results shall be reported as positive with the numerical values printed on the report.

The FTDTL Contractor shall, in coordination with the staff of the State's Department of Information Technology, establish a secure web-based solution that utilizes approved encryption technology to transfer drug test results electronically in a pre-defined text file format. Solution shall include unique user identification and authentication capabilities. The solution shall continuously and automatically check for new records that are ready for submission, and have the ability to re-transmit records, if necessary, within a specified date range. Solution shall flag records upon a successful transmission.

The FTDTL Contractor shall provide technical support for this application, as needed, during State of Maryland business hours.

Reports shall be submitted using a secure web based file transfer solution provided by DBM. This will provide end-to-end file encryption without end-user involvement or third party encryption programs. No additional charges or licensing will be required for authorized end users accessing the secure file transfer application from the Internet.

5. Change/add IFB Section 2.2.9 to read:

Information Technology (IT) Requirements: The FTDTL Contractor shall comply with all aspects of the State IT Security Policy and Standards (http://doit.maryland.gov/support/Pages/SecurityPolicies.aspx) under the following links: State Security Access Control Standard, State Network Security Standard and State Data Encryption Standard. State Categorization, Certification and Accreditation processes shall apply (http://doit.maryland.gov/support/Pages/SecurityCertAccreditation.aspx). Proposed logical and physical technical solution (including security provisions) must be submitted to, and approved in writing by, the Department of Information Technology.

The FTDTL Contractor shall electronically submit sensitive data via a secure web based file transfer solution provided by DBM. This will provide end-to-end file encryption without end-user involvement or third party encryption programs. No additional charges or licensing will be required for authorized end users accessing the secure file transfer application from the Internet.

For reporting to the State and for other Contract IT issues, the FTDTL Contractor shall ensure ongoing compatibility with the State IT systems. Current State specifications are:

- a. Hardware and Software Platforms: Intel 1.8 to 3.00 GHZ, 1 to 3 GB RAM, 80 GB Hard Drive, utilizing Windows XP Professional OS and MS Office Suite 2003;
- b. Web browser: IE 6.0 or higher;
- c. Firewall: Cisco Pix;
- d. Antivirus system: Symantec Antivirus; and
- e. Systems Development Life Cycle Methodology: review http://doit.maryland.gov/policies/Pages/sdlc.aspx

FTDTL Contractor is responsible for following HIPAA Privacy and Security Rules and maintaining reasonable and appropriate administrative, technical, and physical safeguards with regard to the sending and receiving of all information required under the Contract to be awarded under this IFB to:

- ensure the integrity and confidentiality of the information;
- protect against any reasonably anticipated threats or hazards to the security or integrity of the information; and
- protect against any reasonably anticipated unauthorized uses or disclosures of the information.

Data formatting for transmission shall be by a comma-delimited text file. The FTDTL Contractor should contact the Contract Manager to obtain any necessary information to ensure that systems and reporting processes maintain capability for State use and access. The Contract Manager shall notify the FTDTL Contractor of any changes that affect these capabilities. If file transmission specifications change, specific file layout specifications, as well as any additional file transfer processes, will be furnished by the State.

If normal data transmission is interrupted or not available for any reason, the FTDTL Contractor shall **ensure the** submitt**ed** file data is secure file data on a CD-RW disc to the and received by the Contract Manager by overnight mail. The CD-RW disc shall have the latest encryption technology available and that technology shall be updated periodically per the State's guidelines and standards as referenced above. The FTDTL Contractor shall immediately notify the Contract Manager of any such situation and shall provide the Contract Manager with information on the resumption of normal submission of data, as specified by the Contract Manager.

The FTDTL Contractor is responsible for following HIPAA Privacy and Security Rules and maintaining reasonable and appropriate administrative, technical, and physical safeguards with regard to the sending and receiving of all information required under the Contract to be awarded under this IFB.

6. Change IFB Section 3.2.6 (i) to read:

Proof/evidence of compliance with the requirements that the Bidder shall be (i) permitted by the State of Maryland, Department of Health & Mental Hygiene.

<u>Office of Health Care Quality; (ii) CLIA-certified; and (iii) SAMHSA-certified.</u> <u>All three certifications and shall <u>be</u> maintain<u>ed</u> <u>certification from SAMHSA</u> throughout the duration of this Contract.</u>

Date Issued: May 15, 2009 By <signed> .

Mike Yeager

Procurement Officer