

# **Request for Proposal**

**For**

## **Selection of Service Provider**

**To Design, Development, Implementation and  
Maintenance of the web based  
Laboratory Management Information System  
for Food and Drug Laboratory, Vadodara  
(Government of Gujarat)**

**Tender No.: - SWT10102019185**

**BID PROCESSING FEE: Rs. 17,700/- (Non Refundable)**

**EMD: Rs. 2,00,000/- (Refundable)**



**Gujarat Informatics Ltd  
Block No. 2, 2<sup>nd</sup> Floor,  
C & D Wing, Karmayogi Bhavan,  
Sector - 10 A, Gandhinagar - 382010  
Gujarat.  
[www.gil.gujarat.gov.in](http://www.gil.gujarat.gov.in)**

**Last date of receipt of pre-bid queries: 22.10.2019 upto 1500 hrs**

**Date of Pre-Bid Meeting: 22.10.2019 at 1500 hrs**

**Last date of Submission of Bid: 05.11.2019 upto 1500 hrs**

**Opening of Technical Bid: 05.11.2019 at 1600 hrs**

**INDEX**

<b>1</b>	<b>SECTION I: INVITATION FOR BIDS</b> .....	7
1.1	RFP Notice .....	7
1.2	Important Information .....	8
<b>2</b>	<b>SECTION II: INSTRUCTIONS TO BIDDERS (ITB)</b> .....	9
2.1	Source of fund .....	9
2.2	Pre-qualification Criteria.....	9
2.3	Documents Comprising Bid Proposal .....	10
2.4	Eligible Goods and Services .....	11
2.5	Cost of Bidding .....	11
<b>A.</b>	<b>THE BIDDING DOCUMENTS</b> .....	11
2.6	Contents of Bidding Documents .....	11
2.7	Pre-Bid Conference/Clarification of Bidding Documents .....	11
2.8	Amendment of Bidding Documents.....	12
<b>B.</b>	<b>PREPARATION OF BIDS</b> .....	12
2.9	Language of Bid.....	12
2.10	Documents Comprising the Bid .....	12
2.11	Bid Form .....	12
2.12	Bid Prices .....	13
2.13	Bid Currency .....	13
2.14	Bid Security (Ernest Money Deposit) .....	14
2.15	Period of Validity Bids.....	14
2.16	Format and Signing of Bid .....	14
<b>C.</b>	<b>SUBMISSION OF BIDS</b> .....	14
2.17	Contents of Envelope .....	15
2.18	Sealing and Marking of Bids.....	15
2.19	Deadline for Submission of Bids .....	15
2.20	Late Bids .....	15
2.21	Modification and Withdrawal of Bids.....	15
<b>D.</b>	<b>BID OPENING AND EVALUATION OF BIDS</b> .....	15
2.22	Opening of Bids by GIL.....	15
2.23	Clarification of Bids .....	16
2.24	Preliminary Examination.....	16
2.25	Methodology & Criteria for Technical, Commercial and final evaluation .....	16
2.26	Contacting GIL/FDL.....	20
<b>E.</b>	<b>AWARD OF CONTRACT</b> .....	20
2.27	Post-qualification .....	21
2.28	Award Criteria.....	21
2.29	FDL/GIL’s Right to Accept Any Bid and to reject any or All Bids.....	21
2.30	Notification of Awards.....	21

2.31	Signing of Contract .....	21
2.32	Performance Security .....	21
2.33	Key Personnel .....	22
2.34	Evaluations .....	22
2.35	Replacement.....	23
2.36	Corrupt or Fraudulent Practices. ....	23
2.37	Interpretation of the clauses in the Tender Document / Contract Document .....	24
<b>3</b>	<b>SECTION III: GENERAL CONDITIONS OF CONTRACT .....</b>	<b>25</b>
3.1	Definitions.....	25
3.2	Application.....	26
3.3	Use of Contract Documents and Information.....	26
3.4	Intellectual Property Rights (IPR).....	26
3.5	Inspections and Tests .....	27
3.6	Application Security Audit: .....	27
3.7	Delivery and Documents.....	28
3.8	Timeline and Payment Terms: .....	29
3.9	Payment Schedule .....	30
3.10	Payment Procedure.....	32
3.11	Delays in the Supplier’s Performance .....	33
<b>4</b>	<b>SECTION- IV: Service level Agreement and Penalty Clause .....</b>	<b>33</b>
4.1	Definitions.....	33
4.2	Categories of SLAs .....	34
4.3	Implementation related penalty of service levels.....	34
4.4	Operational Related Penalty.....	34
4.5	Termination for Default or Otherwise.....	37
4.6	Force Majeure .....	37
4.7	Transportation .....	38
4.8	Incidental Services .....	38
4.9	Termination for Insolvency .....	38
4.10	Resolution of Disputes .....	38
4.11	Taxes and Duties .....	38
4.12	Binding Clause .....	39
4.13	Limitation of Liability.....	39
4.14	Severability: .....	39
4.15	The FDL, GoG the right.....	39
<b>5</b>	<b>SECTION V: ROLES &amp; RESPONSIBILITIES OF STAKEHOLDERS .....</b>	<b>39</b>
5.1	Food and Drug Laboratory (FDL).....	40
5.2	SI/Bidder: .....	40
<b>6</b>	<b>SECTION VI: Specifications.....</b>	<b>41</b>
6.1	Performance Criteria .....	41

6.2	Availability Criteria .....	41
6.3	Security Criteria .....	42
6.4	Manageability.....	42
6.5	Standards & Protocols.....	42
6.6	Development Criteria .....	43
6.7	Development of Application .....	43
6.8	Development Control .....	43
6.9	Project Management & Project Plan .....	43
6.10	Status Reports.....	44
6.11	System Defects Correction.....	44
6.12	Version Control & Bug Fixing.....	44
6.13	Hosting Criteria.....	44
6.14	Availability.....	44
6.15	Accessibility.....	44
6.16	Security .....	45
6.17	Backup & Recovery .....	45
6.18	Uptime & Performance .....	45
6.19	Access Control and User Authentication: .....	45
<b>7</b>	<b>SECTION VII: SPECIAL CONDITIONS OF CONTRACT .....</b>	<b>46</b>
7.1	Service Provider’s Integrity .....	46
7.2	Service Provider’s Obligations.....	46
7.3	Acceptance Testing and Certification .....	46
<b>8</b>	<b>SECTION VIII: Scope of Work.....</b>	<b>48</b>
8.1	About Food & Drugs Laboratory .....	48
8.2	Objective .....	48
8.3	Overview .....	48
8.4	Functional Requirement .....	50
8.5	Detailed Functional Specification - Phase 1- Core LIMS application .....	55
8.6	Integration with other application .....	75
8.7	Training:.....	75
8.8	Project execution Stages: .....	78
8.9	Operation and Maintenance Support.....	79
<b>9</b>	<b>SECTION IX: Forms of Qualification and Technical Bid .....</b>	<b>83</b>
9.1	Form I: Bid Proposals Form.....	83
9.2	Form II: BIDDER’S CHECK LIST .....	84
9.3	Form III: Particular of Bidders Organization.....	85
9.4	Form IV: Bid Processing Fees & EMD Details .....	86
9.5	Form V: Format for Financial Capability.....	86
9.6	Form VI: Detail of similar type of Project (Successfully Completed or Ongoing).....	86
9.7	Form VII: Work Plan .....	86

9.8	Form IX: Description of the Approach, Methodology and Work Plan for Performing the Assignment.....	87
9.9	Form X: Self-Declaration.....	87
<b>10</b>	<b>Financial Bid Format</b> .....	<b>89</b>
<b>11</b>	<b>Annexure A: Performance Bank Guarantee</b> .....	<b>93</b>
<b>12</b>	<b>Annexure B: Format of Earnest Money Deposit in the form of Bank Guarantee</b> .....	<b>95</b>
<b>13</b>	<b>Annexure C: Format of Affidavit</b> .....	<b>97</b>

### Abbreviations

LIMS	Laboratory Information Management System
FDL	Food and Drug Laboratory
GIL	Gujarat Informatics Limited
SDC	State Data Centre
DST	Department of Science & Technology
ITB	Instruction to Bidder
SI	Total Solution Provide
SI	System Integrator
GOI	Government of India
EMD	Earnest Money Deposit
SD	Security Deposit
HoD	Head of the Department
GoG	Government of Gujarat
GoI	Government of India

## 1 SECTION I: INVITATION FOR BIDS

### 1.1 RFP Notice

On behalf of Food and Drug Laboratory, Government of Gujarat, Gujarat Informatics Limited invites online bids **“To Design, Development, Implementation and Maintenance of the web based LIMS application for the Food and Drug Laboratory, Vadodara”**

For Food and Drug Laboratory actual award of contract will follow the conditions as per this document. This document is given for enabling the bidders to know the tender conditions to guide them in filling up the technical bid and financial bid for the said work.

1. The bidders may download the tender document from website of Gujarat Informatics Limited, <http://gil.gujarat.gov.in> as well as from <https://gil.nprocure.com>.
2. Interested and eligible bidders are required to upload the single Technical and Commercial Bid in two separate sections. The Technical and Commercial Bids should be accompanied by a bid security & bid processing fees (non-refundable) as specified in this Bid Document. The Technical and Commercial Bid must be uploaded to <https://gil.nprocure.com> & the bid security and bid processing fees must be delivered to the office of Gujarat informatics Ltd on or before the last date and time of submission of the bid.
3. This RFP document is not transferable.
4. The consortium will be not allowed.
5. Minimum technical score to qualify for commercial evaluation is 60%.
6. Bidders shall submit **Bid processing fees of Rs. 17,700/-** in the form of Demand Draft in the name of “Gujarat Informatics Ltd.” payable at Gandhinagar along with the covering letter.
7. Bidders shall submit **Bid security/EMD of Rs. 2,00,000/-** in the form of Demand Draft OR in the form of an unconditional Bank Guarantee (which should be valid for 9 months from the last date of bid submission) of any Nationalized Bank including the public sector bank or Private Sector Banks or Commercial Banks or Co-Operative Banks and Rural Banks (operating in India having branch at Ahmedabad/ Gandhinagar) as per the G.R. no. EMD/10/2018/18/DMO dated 16.04.2018 issued/ by Finance Department or further instruction issued by Finance department time to time; in the name of “Gujarat Informatics Ltd.” payable at Gandhinagar (as per prescribed format given in this document) and must be submitted along with the covering letter.
8. The sealed cover should super scribe as “Bid Processing fees & Bid Security/EMD for the Request for Proposal for “To Design, Development, Implementation and Maintenance of the web based LIMS for the Food and Drug Laboratory, Vadodara”

9. Bidders shall submit the affidavit physically at GIL IN ORIGINAL on Non-Judicial Stamp Paper of Rs 100/- duly attested by First Class Magistrate/ Notary public as per GR No. SPO-10-2008-794-CH dated 7th December 2016 of IMD. (as per prescribed format given at Annexure C)

## 1.2 Important Information

Sl. No.	Information	Details
1.	Last date and time for submission of written queries for clarifications to:	nitintatu@gujarat.gov.in dilipk@gujarat.gov.in
2.	Pre-Bid meeting	Conference Room, Block No 2, 2 <sup>nd</sup> Floor, Karmayogi Bhavan, Sector 10-A Gandhinagar
3.	Last date and time for submission of Bid security/EMD & Bid Processing fees at GIL physically	05.11.2019 upto 1500 hrs
4.	Last date and time for submission of proposals (Technical and Commercial) (Online)	05.11.2019 upto 1500 hrs
5.	Place, date and time for opening of Technical proposals	05.11.2019 at 1600 hrs Conference Room, Gujarat Informatics Ltd. Block No. 2, 2 <sup>nd</sup> Floor, C & D Wing, Karmayogi Bhavan, Sector - 10 A, Gandhinagar – 382010- Gujarat.
6.	Place, date and time for technical Presentation	To be intimated later
7.	Contact person for queries	Mr. Nitin Tatu DGM (Application Development), Gujarat Informatics Limited
8.	Address for communication	Deputy General Manager (Application Development) Gujarat Informatics Ltd. Block No. 2, 2 <sup>nd</sup> Floor, C & D Wing, Karmayogi Bhavan, Sector - 10 A, Gandhinagar – 382010- Gujarat.
9.	Place, date and time for opening of financial/commercial proposal	The place, date and time for opening of financial/commercial proposal will be given to the



		technically qualified bidder later.
10.	Bid validity	180 days

10. Technical bids will be opened in the presence of bidders' or their representatives who choose to attend on the specified date and time.
11. Financial bids of only those bidders who got 60% score in technical bids/presentation will be opened.
12. In the event of the date specified for receipt and opening of bid being declared as a holiday for FDL, the due date for submission of bids and opening of bids will be the following working day at the appointed time.
13. Gujarat Informatics Ltd/FDL reserve the right to accept or reject any tender offer without assigning any reason.
14. The document/papers prepared in this connection shall be the property of the FDL/GIL and will have to be deposited with the FDL after the work is over.

## 2 SECTION II: INSTRUCTIONS TO BIDDERS (ITB)

### 2.1 Source of fund

- 2.1.1 Food and Drug Laboratory is calling Selection of Service Provider "To Design, Development, Implementation and Maintenance of the web based LIMS Application"
- 2.1.2 The Work Order will be placed to the selected service provider by FDL directly and the payment for the services mentioned in the said work order will be made directly by FDL from their own sources of funds as per the financial terms and conditions mentioned in this document.

### 2.2 Pre-qualification Criteria

Sr. No.	Pre-Qualification Criteria	Attachments
1	The Bidder should be registered under the Companies Act, 1956, the Partnership Act 1932 or Limited Liability Partnership Act 2008. It should have registered offices in India and should be in existence for at least last 5 years, as on last date of submission of bids.	Certificate of Registration
2	The Bidder Should have CMMi (level 3 or above) or ISO 9001:2015 in IT Software development related Services	Copy of Valid Certification
3	The bidder must have turnover of at least Rs. 2 crore for each of the last	Audited and Certified Balance Sheet & Profit/Loss Account of

	three financial years or cumulative of Rs. 6 crores in last three years as on 31st March, 2019 from Software/IT product Development and Software Support service activities. It should not include Hardware procurement & Third party software license procurements.	last 3 Financial Years with CA certificate mentioning turnover from Software/IT product Development and Software Support service activities
4	Bidder should have completed at least 3 projects of web application or web portal development & maintenance project and at least 1 completed/ongoing project for LIMS (Excluding Hardware and Manpower) each of value more than 40 lacs in the last 5 years.	A copy of the work order/Contract Agreement with Client Completion Certificate for each of the projects undertaken to be submitted.
5	The Bidders should not be under a declaration of ineligibility for corrupt and fraudulent practices issued by Government of Gujarat and / or black-listed by Gujarat Government departments from last 5 years as on last date of submission of bids.	Self-Declaration as attached / affidavit
6	The bidder must have one office in Gujarat. In case, bidders do not have office in Gujarat, bidder should give undertaking to open office in Gujarat within 45 days from the date of empanelment.	Please attach the copy of any two of the following: Property tax bill/Electricity Bill/Telephone Bill/VAT/CST/GST Registration/Lease agreement.
7	No Consortium will be allowed.	-

### 2.3 Documents Comprising Bid Proposal

The response submitted by the bidder shall comprise the following documents:

#### 2.3.1 Qualification & Technical Proposal

- 2.3.1.1 Sealed cover of Bid Processing Fee and Earnest Money Deposit/Bid Security
- 2.3.1.2 Bid Proposal form
- 2.3.1.3 General Information
- 2.3.1.4 Financial Capability with supporting documents
- 2.3.1.5 Relevant Experience with supporting documents
- 2.3.1.6 Self-Declaration
- 2.3.1.7 All relevant Certification
- 2.3.1.8 All undertakings submitted by the Authorized Signatory shall be on a Stamp Paper of value not less than Rs.100
- 2.3.1.9 Proposal document containing a brief about the organization, its expertise and documentary evidences.

#### 2.3.2 Financial Proposal

**2.4 Eligible Goods and Services**

**2.4.1** Software application development and deployment with or without configuration to suit the customer’s specific process requirements. Software shall be implementable or deployable and maintainable by any other competent agency. Software solution shall also be available with complete transparency including operation manuals, help documents and source code.

**2.4.2** For purpose of this clause, "origin" means the place where the goods are from or from which the ancillary services are supplied. Goods are produced when, through manufacturing, processing, code writing and compiling, or substantial or major assembling of components, a commercially recognized product results that is substantially different in basic characteristics or in purpose or in purpose or utility from its components.

**2.5 Cost of Bidding**

**2.5.1** The bidder shall bear all the costs associated with the preparation and submission of its bid, and GIL will in no case be responsible or liable for these costs, regardless of conduct or outcome of bidding process.

**A. THE BIDDING DOCUMENTS**

**2.6 Contents of Bidding Documents**

**2.6.1** The goods required, bidding procedure and contract terms are prescribed in the bidding documents.

**2.6.2** The bidder is expected to examine all instructions, forms, terms and specifications in the bidding documents. Failure to furnish all information required by the bidding documents in format or submission of a bid not substantially responsive to the bidding documents in every respect will be at the Bidder’s risk and may result in rejection of its bid.

**2.7 Pre-Bid Conference/Clarification of Bidding Documents**

**2.7.1** A prospective bidder requiring any clarification of the bidding documents may seek clarifications of his/her queries submitted on or before date mentioned in section 1 for submission of pre-bid queries. GIL/FDL will discuss the queries received from the interested bidders in the pre-bid meeting and respond the clarifications by uploading on the website. The interested bidder should send the queries as per the following format:

Bidder’s Request for Clarification			
Name of Organization submitting request		Name & position of person submitting request:	Address of organization including phone, fax, email points of contact
S.No.	Bidding Document Reference (Clause /page)	Content of RFP requiring clarification	Points of Clarification required

1			
2			
3			
4			

## **2.8 Amendment of Bidding Documents**

- 2.8.1** At any time prior to the deadline for submission of bids, FDL/GIL may, for any reason, whether on its own initiative or in response to a clarification request by a prospective bidder, modify the bidding documents.
- 2.8.2** All prospective bidders who have received the bidding documents will be notified of the amendment through website and such amendments will be binding on them.
- 2.8.3** To allow prospective bidders reasonable time to consider the amendments while preparing their bids, FDL/GIL at its discretion, may extend the deadline for the submission of bids.

## **B. PREPARATION OF BIDS**

### **2.9 Language of Bid**

- 2.9.1** The proposal prepared by the bidder, as well as all correspondence and documents relating to the bid exchanged by the bidder and GIL shall be in English language.

### **2.10 Documents Comprising the Bid**

- 2.10.1** The bid prepared by the bidder shall comprise of the following documents:
- 2.10.2** Technical Bid and a Financial Bid completed in accordance with ITB Clauses 2.9, 2.10 and 2.11
- 2.10.3** Bid security furnished in accordance with ITB Clause 2.14.
- 2.10.4** The bid security as mentioned in Section 1, document processing fee & bid security (earnest money deposit) are to be submitted in physical form in the form of Demand Draft favoring “Gujarat Informatics Ltd” payable Gandhinagar.
- 2.10.5** The Qualification Criteria, Technical Bid and Financial Bid must be submitted online through the e-Tendering website of <https://gil.nprocure.com> using digital signatures.

### **2.11 Bid Form**

- 2.11.1** The Bidder shall complete the Technical Bid and a Financial Bid furnished with this document giving details as per the format mentioned in the e-Tendering website <https://gil.nprocure.com>.

## **2.12 Bid Prices**

- 2.12.1** The bidder shall indicate the prices in the format mentioned in the Financial Bid.
- 2.12.2** The following points need to be considered while indicating prices:
- 2.12.2.1** The prices quoted should also include, inland transportation, insurance and other local costs incidental to delivery of the goods and services to their destination within the state of Gujarat
  - 2.12.2.2** The rates of any Indian duties, GST and other taxes which will be payable by the client on the goods/services (if any) if this contract is awarded, should be quoted separately.
  - 2.12.2.3** Invoicing shall be from Gujarat only.
- 2.12.3** The Bidder's separation of the price components in accordance with the ITB Clause 7.2 above will be solely for facilitating the comparison of bids by GIL and will not in any way limit the Client's right to contract on any of the terms offered.
- 2.12.4** Sharing of responsibility (between FDL and the bidder) of procurement of various types of software shall be as under:
- 2.12.5** The prices quoted shall be inclusive of license software required for actual running of applications developed at Central Level.
- 2.12.6** FDL shall procure or provide the required software platform at user level for running of products like user level operating system, and system software etc.
- 2.12.7** The SI will provide and develop software to run environment mentioned in scope of work at the central side and for database management.
- 2.12.8** The price quoted shall be inclusive of development of software and operation & maintenance support for the period of contract with required number of copies of the licensed version used/proposed for the purpose. This shall also include the cost of integration with applicable modules of integrated solutions.
- 2.12.9** Bidder is expected to fill the rates/amount for all items in Financial Bid format. However, in case, the bidder chooses to quote zero, nil amount or blank, it will be his risk and the same shall in no way restrict the scope of the work. Any rate quote field kept blank would imply that bidder is quoting zero prices for that item.
- 2.12.10** The full IPR for the entire software will rest with the FDL. The same would be applicable to copyrights. The SI shall sign any/all the documents in this regard and hand over the source code, Meta data details etc. to the FDL before release of final payment on completion of training and implementation of solution.

## **2.13 Bid Currency**

- 2.13.1** Prices shall be quoted in Indian Rupees only.

## **2.14 Bid Security (Ernest Money Deposit)**

**2.14.1** Bidders shall submit Bid security/EMD of Rs. 2,00,000/- in the form of Demand Draft OR in the form of an unconditional Bank Guarantee (which should be valid for 9 months from the last date of bid submission) of any Nationalized Bank including the public sector bank or Private Sector Banks or Commercial Banks or Co-Operative Banks and Rural Banks (operating in India having branch at Ahmedabad/ Gandhinagar) as per the G.R. no. EMD/10/2018/18/DMO dated 16.04.2018 issued/ by Finance Department or further instruction issued by Finance department time to time; in the name of “Gujarat Informatics Ltd.” payable at Gandhinagar (as per prescribed format given in this document) and must be submitted along with the covering letter.

**2.14.2** Proposals not accompanied by EMD shall be rejected as non-responsive.

**2.14.3** The successful bidder’s bid security will be discharged from GIL only after the signing of the contract and submission of performance security.

**2.14.4** Unsuccessful bidder’s EMD will be discharged / refunded as promptly as possible, but not later than 30 days of the validity period of the bid.

**2.14.5** The EARNEST MONEY DEPOSIT shall be forfeited:

- a) If a bidder withdraws its bid during the period of bid validity specified by the bidder on the bid form;
- b) Or in case of a successful Bidder, if the Bidder fails to sign the Contract; or to furnish the performance security.

**2.14.6** No exemption for submitting the EMD will be given to any agency.

## **2.15 Period of Validity Bids**

**2.15.1** Bids shall be valid for 180 days after the date of bid opening of Financial Bid. The GIL/FDL shall reject a bid valid for a shorter period as non-responsive.

**2.15.2** In exceptional circumstances, the tendering authority may solicit the bidder’s consent to an extension of the period of validity. The request and the responses there to shall be made in writing.

**2.15.3** Bid evaluation will be based on the bid prices without taking into consideration the above changes.

## **2.16 Format and Signing of Bid**

**2.16.1** The bidders must submit the bid on the e-Tendering website <https://gil.nprocure.com>. All supporting documents in the form of scanned copies submitted online should have sign and seal of the bidder.

**2.16.2** Before filling in any of the details asked, bidders should go through the entire bid document and get the required clarifications from GIL/FDL during the pre-bid conference.

## **C. SUBMISSION OF BIDS**

## **2.17 Contents of Envelope**

**2.17.1** Envelope for the EMD and Bid Processing Fee.

**2.17.2** Envelope shall be marked as Envelope for “EMD & Bid Processing Fee for the tender for ‘To Design, Development, Implementation and Maintenance of the web based LIMS application for FDL”

## **2.18 Sealing and Marking of Bids**

**2.18.1** All bids must be submitted online through <https://gil.nprocure.com> as per the formats mentioned therein using digital signatures.

**2.18.2** Telex, cable, e-mailed or facsimile bids will be rejected.

## **2.19 Deadline for Submission of Bids**

**2.19.1** Bids must be submitted online not later than the time and date specified in the Invitation for Bids (Section I). In the event of the specified date for the submission of bids being declared as a holiday for GIL, the bids will be received up to the appointed time on the next working day.

**2.19.2** GIL may, at its discretion, extend this deadline for submission of bids by amending the bid documents with ITB Clause 2.6, in which case all rights and obligations of GIL and bidders previously subject to the deadline will thereafter be subject to the deadline as extended.

## **2.20 Late Bids**

**2.20.1** Late bids will be rejected and returned unopened to the bidder.

## **2.21 Modification and Withdrawal of Bids**

**2.21.1** The bidder may modify or withdraw his bid before the last date of submission of bids through the e-Tendering website <https://gil.nprocure.com>.

**2.21.2** No bid may be modified after the deadline for submission of bids.

**2.21.3** No bid may be withdrawal in the interval between the deadline for submission of bids and the expiration of the period of the bid validity specified by the Bidder on the Bid Form. Withdrawal of a bid during this interval may result in the Bidder’s forfeiture of its bid security, pursuant to ITB Clause 2.15.

## **D. BID OPENING AND EVALUATION OF BIDS**

### **2.22 Opening of Bids by GIL**

**2.22.1** GIL will open all bids (only eligibility stage at the first instance), in the presence of bidder or his representative who choose to attend, and at the following address:

**DGM (App)  
Gujarat Informatics Ltd,  
Block No. 2, 2<sup>nd</sup> Floor,  
C & D Wing, Karmayogi Bhavan,  
Sector - 10 A, Gandhinagar – 382010**

The bidder's representative who is present shall sign an attendance register evidencing their attendance. In the event of the specified date of bid opening being declared holiday for GIL office, the bid shall be opened at the appointed time and location on the next working day.

**2.22.2** The Bidder's names, bid modifications or withdrawal, bid prices, discounts, and the presence or the absence of requisite bid security and such other details, as GIL, at its discretion, may consider appropriate, will be announced at the time of opening.

**2.22.3** Bids that are not opened and read out at bid opening shall not be considered for further evaluation, irrespective of the circumstances.

**2.22.4** Financial Bids of only those bidders who qualify based on evaluation of technical bid will be opened in the presence of the qualified bidders of their representatives at pre-specified time and date which will be communicated to the qualified bidders well in advance.

### **2.23 Clarification of Bids**

**2.23.1** During evaluation of bids, GIL/FDL may, at its discretion, ask the Bidder for a clarification of its bid. GIL/FDL may also ask for rate analysis of any or all items and if rates are found to be unreasonably low or high, the bid shall be treated as non-responsive and hence liable to be rejected. The request for a clarification and the response shall be in writing and no change in prices or substance of the bid shall be sought, offered or permitted.

### **2.24 Preliminary Examination**

**2.24.1** GIL will examine the bids to determine whether they are complete, whether any computational errors have been made, whether sureties have been furnished, whether the documents have been properly signed, and whether the bids are generally in order.

**2.24.2** Prior to the detailed evaluation, pursuant to ITB Clause 2.25, GIL will determine the substantial responsiveness of each bid to the bidding documents. For purposes of these Clauses, a substantially responsive bid is one, which confirms to all the terms and conditions of the bidding documents without material deviation

**2.24.3** If a Bid is not substantially responsive, it will be rejected by GIL/FDL and may not subsequently be made responsive by the Bidder by correction of the non-conformity.

**2.24.4** Conditional bids are liable to be rejected.

### **2.25 Methodology & Criteria for Technical, Commercial and final evaluation**

**2.25.1** For technical evaluation and comparison of the bids, which have been determined to be substantially responsive pursuant to ITB clause 2.24, GIL



will evaluate the technical bid as per the assessment procedure given in GR No. TSP-2004-808-DST dated 30/07/2004. The committee will scrutinize techno-commercial offers and evaluate capability of bidders through presentations, demonstration, documents. etc.

**2.25.2** The bidders are expected to provide all the required supporting documents & compliances as mentioned in this RFP. The bidder shall quote having full compliance with all the guiding principles and minimum specifications as mentioned in this RFP. Any deviation from the same will lead to the disqualification.

**2.25.3** The technical evaluation of bids will be done based on following three components only for those bidders who satisfy all the Eligibility Criteria (ITB Clause No. 2)

- Technical Bid Document
- Approach & Methodology Document
- Presentation on Approach & Methodology for provided Solution

**2.25.4** During the technical evaluation, GIL/FDL may seek the clarification in writing from the bidder, if required. If bidder fails to submit the required clarifications in due time, the technical evaluation will be done based on the information submitted in the technical bid. The price bid will be opened of the bidders whose technical bids are fully complied and who have scored 60% in technical evaluation. At any point of time, if GIL/FDL feels that the bidder is hiding any information which will affect the project cost in short or long run, GIL/FDL may reject his bid without assigning any reason or explanation.

**2.25.5** Price quoted in the financial bid will be final. Bidder is required to fulfill all obligations as required in the bid as per the prices quoted in the financial bid, for the proposed scope of work and bill of material, applicable taxes or missing component(s), if any for which the description is there in technical response, but price is not provided in the financial sheet. Price will be appropriately loaded for the missing tax components/missing components that in the understanding of the evaluators is found to be missing from the proposed bill of material except in case where there is a written justification provided in the technical bid response. Basis of loading shall be the highest cost quoted by the bidders.

**2.25.6** For evaluation of Financial Bids, the without tax values will only be considered for comparison.

**2.25.7** The following criteria shall be used to evaluate the technical bids.

Sr. No.	Criteria	Max Points	Point system	Document Required
1	No. of years since the bidder is engaged in similar IT projects/solutions business, (as on bid submission date)	05	<ul style="list-style-type: none"> <li>• up to 5 years – 3 points</li> <li>• &gt;5 years – 5 points</li> </ul>	Copy of client Certificate + Work Order
2	Average Turnover of firm/ company in last three financial years (in Rs.) as on 31st March, 2019 from Software development and support Service activities.	05	<ul style="list-style-type: none"> <li>• 2 crores to 5 Crore – 3 points</li> <li>• &gt;5 crores – 5 points</li> </ul>	Audited and Certified Balance Sheet & Profit/Loss Account of last 3 Financial Years with CA certificate mentioning turnover from Software/IT product Development and Software Support service activities
3	Quality Certifications	05	<ul style="list-style-type: none"> <li>• ISO 9001:20015 or latest for software development or CMMI 3 or above =3 points</li> <li>• If both = 5 points</li> </ul>	Quality Certificates
4	Completed Projects of web based portal/application development of more than Rs. 40 Lacs in last five years.	05	<ul style="list-style-type: none"> <li>• 3 to 5 projects – 3 points</li> <li>• &gt; 5 projects- 5 points</li> </ul>	Completion Certificates from the client + Work Order
5	No. of “similar” Laboratory Management System Development projects completed/ongoing in last 5 years as on bid submission date, each of value more than 40 lakh	10	<ul style="list-style-type: none"> <li>• at least 1 project = 04 Marks</li> <li>• 2 to 4 projects = 07 Marks</li> <li>• &gt;4 projects = 10 Marks</li> </ul>	Completion Certificates from the client + Work Order
6	Technical Presentation	70	As per 2.25.8	
	<b>Total</b>	<b>100</b>		
	<b>Minimum Qualifying Marks</b>	<b>60</b>		

### 2.25.8 Technical Presentation

On the prescribed date and time, the bidder shall make a technical presentation covering following areas:

S No.	Parameter	Marks
1.	Understanding of Scope of Work	10
2.	Proposed Solution <ul style="list-style-type: none"><li>• Tools/Technologies used for design, development and customized etc., security, conformance to industries standard</li><li>• Development and deployment architecture</li></ul>	20
3.	Implementation Strategy (Approach & Methodology), Project Plan, Data management and migration strategy), Scalability of Software, Risk and mitigation Plan, Plan to handle multiple stakeholders	10
4.	Proposed Team for project (Development, Deployment and O & M)	10
5.	Ease of Usage, Ease of Customization, Modular approach. Methods of report generation including method of exporting the same	15
6.	Value Addition	5
<b>TOTAL</b>		<b>70</b>

### 2.25.9 **Technical Bid Evaluation:**

The technical score of a bidder 'Tb' will be assigned to the bidder & it will be awarded based on the Technical Evaluation Criteria as specified above. FDL/GIL's decision in this regard shall be final & binding and no further discussion will be held with the bidders whose bids are technically disqualified / rejected. Bidders with technical score of 60 and above will qualify for the evaluation in the commercial bids. The total technical scores achieved by the bidders shall be shared with the bidders & under any circumstances the breakup of the technical score shall not be shared with the bidders.

Tb: Absolute Technical Score

Tmax: Maximum Technical Score

Tn: Normalized technical score of the bidder under Consideration

Normalized technical score (Tn) =  $Tb/Tmax * 100$

### 2.25.10 **Financial Bid evaluation:**

The financial bids of only those bidders, who have scored at least 60 marks in the technical evaluation process, will be opened. The Financial Bids will be opened, in the presence of Bidders' representatives who choose to attend the Financial Bid opening on date and time to be communicated to all the technically qualified Bidders. The Bidder's representatives who are present shall sign a register evidencing their attendance. The name of bidder & bid

prices will be announced at the meeting. The financial score of a bidder 'Fb' will be assigned to the bidder. 'Fb' will be the total financial quote made by the bidder (excluding the Optional Services quotes sought in the financial bid)

$F_n$  = normalized financial score for the bidder under consideration

$F_b$  = commercial quote for the bidder under consideration

$F_{min}$  = commercial quote of the lowest evaluated financial proposal

The lowest evaluated Financial Proposal ( $F_{min}$ ) will be given the maximum financial score ( $F_n$ ) of 100 points. The financial scores ( $F_n$ ) of the other Financial Proposals will be calculated as per the formula for determining the financial scores given below:

$$\text{Normalized Financial Score } (F_n) = 100 \times F_{min} / F_b$$

#### **2.25.11 Final Evaluation of Bid**

Proposals will be ranked according to their combined technical ( $T_b$ ) and financial ( $F_n$ ) scores using the weights ( $T = 0.40$  the weight given to the Technical Proposal;  $P = 0.60$  the weight given to the Financial Proposal;  $T + P = 1$ ). The final evaluation will be based on Final Score which shall be calculated as shown below:

$$\text{Final Score } (S) = T_n \times T + F_n \times P$$

The bidder achieving the highest combined technical and financial score will be invited for negotiations for awarding the contract. In case of a tie where two or more bidders achieve the same highest combined technical and financial score, the bidder with the higher normalized technical score will be invited first for negotiations for awarding the contract.

#### **2.26 Contacting GIL/FDL**

**2.26.1** Subject to ITB Clause 2.23, no Bidder shall contact FDL on any matter relating to its bid, from the time of the bid opening to the time of contract is awarded. If he wishes to bring additional information to the notice of FDL, he should do so in writing. FDL reserves its right as to whether such additional information should be considered or otherwise. Any effort by a Bidder to influence GIL/FDL in its decision on bid evaluation, bid comparison or contract award may result in disqualification of the Bidder's bid and forfeiture of his bid security amount.

### **E. AWARD OF CONTRACT**

## **2.27 Post-qualification**

**2.27.1** An affirmative determination will be a prerequisite for the award of the contract to the Bidder. A negative determination will result in rejection of Bidder's bid, in which event the department will proceed to the next lowest evaluated bid to make a similar determination of the Bidder's capabilities to perform the contract satisfactorily.

## **2.28 Award Criteria**

**2.28.1** Subject to ITB Clause 2.33, FDL will award the contract to the successful bidder as per the evaluation procedure mentioned in ITB clause no. 2.25 mentioned above.

**2.28.2** FDL reserves the right to award the contract to the bidder whose bid may not have been determined as the lowest evaluated bid, provided further that the bidder is determined to be qualified to perform the contract satisfactorily.

## **2.29 FDL/GIL's Right to Accept Any Bid and to reject any or All Bids**

**2.29.1** FDL/GIL reserve the right to accept or reject any bid, and to cancel the bidding process and reject all bids at any time prior to award of Contract, without thereby incurring any liability to the affected Bidder or bidders or any obligation to inform the affected Bidder or bidders of the grounds for FDL/GIL action.

## **2.30 Notification of Awards**

**2.30.1** Prior to the expiration of the period of the bid validity, concerned GIL/FDL will notify the successful bidders in writing, to be confirmed in writing by registered letter, that his bid has been accepted.

**2.30.2** The notification of award will constitute the formation of the Contract.

**2.30.3** Upon the successful Bidder's furnishing of performance security pursuant to clause 33, FDL/GIL will promptly notify each unsuccessful bidder.

## **2.31 Signing of Contract**

**2.31.1** At the same time as GIL/FDL notifies the successful Bidder that its bid has been accepted, FDL will send the bidder the Contract Form, incorporating all the agreements between two parties.

**2.31.2** Within 15 days of receipt of the contract form, the successful bidder shall sign and date the contract and return it to GIL/FDL.

## **2.32 Performance Security**

**2.32.1** The successful Bidder has to furnish a security deposit so as to guarantee his/her (Bidder) performance of the contract

**2.32.2** The Performance Bank Guarantee (PBG) has to be submitted within fifteen (15) working days of receipt of award. The PBG shall be 10% of the contract value of projects and valid up to 180 days beyond the expiry of contract.

- 2.32.3** The PBG shall be denominated in Indian Rupees and shall be in the form of a Bank Guarantee issued by any Nationalized Bank including the public sector bank or Private Sector Banks or Commercial Banks or Co-Operative Banks and Rural Banks (operating in India having branch at Ahmedabad/Gandhinagar) as per the G.R. no. EMD/10/2018/18/DMO dated:16/04/2018 issued by Finance Department or further instruction issued by Finance department time to time. (The draft of Performance Bank Guarantee is attached herewith).
- 2.32.4** The proceeds of the Performance Bank Guarantee shall be payable to the Department as compensation for any loss arising from the bidder(s)'s failure to complete its obligations under the contract.
- 2.32.5** The Performance Bank Guarantee will be discharged by the Department and returned to the bidder(s) on completion of the bidder's performance obligations under the contract.
- 2.32.6** In the event of any contract amendment, the bidder shall, within 21 days of receipt of such amendment, furnish the amendment to the Performance Bank Guarantee, rendering the same valid for the duration of the contract, as amended for further period.
- 2.32.7** No interest shall be payable on the PBG amount. FD may invoke the above bank guarantee for any kind of recoveries, in case; the recoveries from the bidder exceed the amount payable to the bidder.

### **2.33 Key Personnel**

- 2.33.1** Appointed SI must provide details of Key personnel to be deployed to carry out project as per Team composition and CV given as part of Technical bid.
- 2.33.2** SI shall ensure that each member of the Key Personnel devotes substantial working time to perform the services to which that person has been assigned as per the proposal.
- 2.33.3** SI shall use commercially reasonable efforts to ensure it retains the services of its Key Personnel, including provisioning of competitive compensation, benefits and other conditions to its Key Personnel so as to incentivize them to remain in SI's employment.
- 2.33.4** SI shall not make any changes to the composition of the Key Personnel and not require or request any member of the Key Personnel to cease or reduce his or her involvement in the provision of the Services during the Term (or agree to any request other than from department that would have the same effect):
- a) unless that person resigns, is terminated for cause, dies, is long-term disabled, is on permitted mandatory leave under Applicable Law or retires; or
  - b) Without department prior written consent.

### **2.34 Evaluations**

- 2.34.1** SI shall carry out an evaluation of the performance of each member of the Key Personnel in connection with the Services at least once in each Contract Year.

SI shall provide reasonable written notice to GIL/FDL of the date of each evaluation of each member of the GIL/FDL shall be entitled to provide SI with input for each such evaluation.

**2.34.2** SI shall promptly provide the results of each evaluation to GIL/FDL subject to Applicable Law.

### **2.35 Replacement**

**2.35.1** In case of absent of the manpower, bidder has to provide the alternate arrangement to carry out the activities.

**2.35.2** In case the resource has resigned then the bidder has to inform within one week of such resignation.

**2.35.3** SI shall promptly deploy a replacement to ensure that the role of any member of the Key Personnel is not vacant for any longer than 7 days, subject to reasonable extensions requested by SI Vendor

**2.35.4** Before assigning any replacement member of the Key Personnel to the provision of the Services, SI shall provide:

- a) a resume, curriculum vitae and any other information about the candidate that is reasonably requested ; and
- b) an opportunity to interview the candidate.

**2.35.5** The bidder has to ensure at least 4 weeks of overlap period in such replacements

### **2.36 Corrupt or Fraudulent Practices.**

**2.36.1** GIL/FDL requires that the bidders under this tender observe the highest standards of ethics during the procurement and execution of such contracts. In pursuance of this policy, GIL/FDL defines for the purposes of this provision, the terms set forth as follows:

- a) “Corrupt practice” means the offering, giving, receiving or soliciting of anything of value to influence the action of the GIL/FDL official in the procurement process or in contract execution; and
- b) “Fraudulent practice” means a misrepresentation of facts in order to influence a procurement process or a execution of a contract to the detriment of GIL/FDL, and includes collusive practice among bidders (prior to or after bid submission) designed to establish bid prices at artificial noncompetitive levels and to deprive GIL/ FDL of the benefits of the free and open competition.

**2.36.2** GIL/FDL shall reject a proposal for award if it determines that the Bidder recommended for award has engaged in corrupt or fraudulent practices and same shall be conveyed to GIL or black listed by any of the GIL/Government of Gujarat in competing for the contract in question.

**2.36.3** GIL/FDL shall declare a firm ineligible, and black listed either indefinitely or for a stated period of time, to be awarded a contract if it at any time

determines that the firm has engaged in corrupt and fraudulent practices in competing for, or in executing, a contract. The same shall be conveyed to GIL.

**2.37 Interpretation of the clauses in the Tender Document / Contract Document**

**2.37.1** In case of any ambiguity in the interpretation of any of the clauses in Bid Document or the Contract Document, the GIL/FDL interpretation of the clauses shall be final and binding on all parties.

**2.37.2** However, in case of doubt as to the interpretation of the bid, the bidder may make a written request prior to the date of clarifications and doubts conference to:

- a) DGM (Application Development)  
Gujarat Informatics Ltd,  
Block No. 2, 2nd Floor,  
C & D Wing, Karmayogi Bhavan,  
Sector - 10 A, Gandhinagar - 382010  
Gujarat.

**2.37.3** GIL/ FDL may issue clarifications to all the bidders as an addendum. Such an addendum shall form a part of the bid document.



### 3 SECTION III: GENERAL CONDITIONS OF CONTRACT

#### 3.1 Definitions

(In this Contract, the following terms shall be interpreted as indicated)

- a) “Applicable Law” means the laws and any other instruments having force of law in India from time to time.
- b) “Proposal/bid” means proposal submitted by bidders in response to the RFP issued by GIL for selection of Service Provider “To Design, Development, and Implementation of the web based LIMS for FDL”
- c) “Competent Authority” means the Food and Drug Laboratory (FDL), Vadodara.
- d) “Committee” means committee formed by the FDL for the purposes of processing and evaluation of this bid
- e) “Contract Value” means the price payable to the selected firm/company under the Contract for the complete and proper performance of its contractual obligations.
- f) “Service Provider” means any private or public entity, which will provide the services to FDL under the contract.
- g) “Contract” means the Contract signed by the parties along with the entire documentation as specified in the RFP
- h) “Day” means Working day.
- i) The “Bid Document” and “Tender Document” are same
- j) “Effective date” means the date from which the contract comes into force and effect.
- k) “Government” means State Government of Gujarat.
- l) “FDL” means Food and Drug Laboratory, Vadodara, Government of Gujarat.
- m) “Product” means a final solution after Development/Customization of application as per requirement of the FDL.
- n) “Rules” means the applicable rules under different statutes, Acts, Rules, Government Resolutions, Circulars in relation to personal management of employees in Gujarat Government.
- o) “GIL” means Gujarat Informatics Limited, C & D Wing, Block No:2, 2<sup>nd</sup> Floor Karmayogi Bhavan, Sector-10(A), Gandhinagar, Gujarat.
- p) “Personnel” means professional and support staff provided by the SI and assigned to perform services to execute an assignment and any part thereof.
- q) “Services” means the work to be performed by the SP pursuant to the selection by FDL and to the contract to be signed by the parties in pursuance of any specific assignment awarded to them by FDL.

- r) “Go-Live” means Date on which the product is made operational on the production environment and becomes available for use to all the identified stakeholders of the project post successful completion to the satisfaction of FDL of acceptance testing by the 3rd party audit agency or any other agency/group designated by FDL.

### **3.2 Application**

- 3.2.1 These General Conditions shall apply to the extent that they are not superseded by provisions in other parts of the Contract.

### **3.3 Use of Contract Documents and Information**

- 3.3.1 The service provider shall not, without FDL prior written consent, disclose the Contract, or any provision thereof, or any specification, plan, drawing, pattern, sample or information furnished by or on behalf of the in connection therewith, to any person other than a person employed by the service provider in performance of the Contract. Disclosure to any such employed person shall be made in confidence and shall extend only so far as may be necessary for purposes of such performance.
- 3.3.2 Any document, other than the Contract itself, enumerated in GCC Clause 5.1 shall remain the property of FDL and shall be returned (in all copies) to FDL on completion of the service provider’s performance under the Contract if so required by FDL.
- 3.3.3 The service provider shall permit FDL to inspect the service provider’s accounts and records relating to the performance of the service provider and to have them audited.

### **3.4 Intellectual Property Rights (IPR)**

- 3.4.1 The application developed by Service Provider under the contract will be the exclusive property of GIL/FDL.
- 3.4.2 The IPR/Source code of all the software code, data, algorithms, documentations, manuals, any other documents etc. generated as part of development of this project shall solely rest with FDL, Govt. of Gujarat. There would be a property of FDL.
- 3.4.3 All the deliverable and Application Software developed by service provider for FDL, then the copyright/IPR of that software/deliverable will be with the FDL. The bidder shall not sell or use (fully/partly) that software for service of other customers without written consent from FDL, Government of Gujarat.
- 3.4.4 While passing on the rights (license) of using any software/software tool, the service provider shall ensure that such rights are inclusive of the use of that software for development in addition to deployment and the cost of the same should be included in the financial bid.
- 3.4.5 The software licenses supplied by service provider shall be genuine, perpetual, full use and should provide patches, fixes, security updates directly from the OEM at no additional cost to the FDL for the entire period of contract. All the

licenses and support should be in the name of Food and Drug Laboratory from the date of procurement.

- 3.4.6** The service provider shall indemnify FDL against all third-party claims of infringement of copyright, patent, trademark or industrial design rights arising from use of the Goods or any part thereof in India.
- 3.4.7** In the event of any claim asserted by a third party of infringement of copyright, patent, trademark or industrial design rights arising from the use of the Goods or any part thereof in India the service provider shall act expeditiously to extinguish such claim. If the service provider fails to comply and FDL is required to pay compensation to a third party resulting from such infringement, the service provider shall be responsible for the compensation including all expenses, court costs and lawyer fees. FDL will give notice to the service provider of such claim, if it is made, without delay.
- 3.4.8** The FDL shall have the unrestricted right to deploy or application software and the documentation related thereto, in any Gujarat state government department, at no cost to client.

### **3.5 Inspections and Tests**

- 3.5.1** FDL/GIL or its representative shall have the right to inspect and/or to test the software or work of the service provider to confirm their conformity to the Contract specifications at no extra cost to FDL.
- 3.5.2** As per Govt. Of Gujarat circular dated 10<sup>th</sup> March 2006, the FDL applications must be tested at EQDC, GIDC, Gandhinagar or at the location specified by FDL at the cost of SI. The different types of below mentioned tests that has to be performed through EQDC.
- Functional testing,
  - Stress/Load testing,
  - Performance testing,

### **3.6 Application Security Audit:**

In addition to inspection & testing, the SI shall also be responsible to get application security audited by CERT-In Empaneled application security auditors at the cost of the SI and submit the Security Audit Clearance Certificate issued by CERT-In Empaneled Security Auditors.

- a) The SI must submit the test results to FDL.
- b) Should any inspected or tested software fail to conform to the specifications, the FDL may reject the software and the SI shall either replace/redevelop the rejected software or make alterations necessary to meet specification requirements free of cost to FDL.
- c) FDL's right to inspect, test and, where necessary, reject the software / deliverable after the software deployment at project site shall in no way be limited or waived by reason of the software previously been inspected,

tested and passed by FDL for its representative prior to the software deployment.

- d) No clause in the RFP document releases the SI from any warranty or other obligations under this Contract.
- e) The inspection of the working of the developed software shall be carried out to check whether the software is in conformity with the requirements described in the contract. The tests will be performed after completion of installation and commissioning of all the software at the site of installation. During the test run of software, no malfunction, partial or complete failure of any module of software or bugs in the software is expected to occur. All the software should be complete and no missing modules/sections will be allowed. The SI shall maintain necessary logs in respect of the result of the test to establish to the entire satisfaction of FDL, the successful completion of the test specified. An average uptime efficiency of 99% for the duration of test period shall be considered as satisfactory. On successful completion of acceptability test and after FDL is satisfied with the working of the software on the, the acceptance certificate of FDL will be issued. The date on which such certificate is signed shall be deemed to be the date of successful commissioning of the software.
- f) Before the Application modules are taken over by FDL, the SP shall supply operation manuals and technical design and development documents. These shall be in such details as will enable FDL to use the software as stated in the specifications. The documentation shall be in English/Gujarati language and in such form and numbers as stated in the contract document. Unless and otherwise agreed, the software shall not be considered to be complete for the purpose of taking over until such documentation has supplied to FDL.

### **3.7 Delivery and Documents**

The SI shall prepare all necessary documentation for the project, and provide them to the FDL for review, approval, record, reference etc as mentioned in this RFP. The following is the list of deliverables (but not limited to) in the form of documents to be submitted by the SI in the course of project implementation.

- As-Is Process Report for all the processes of services.
- Business Process Re-engineering report for the all the services of FDL.
- To-Be process map based on the BPR report.
- User Requirement Specification documents for all the selected processes.
- System Requirement Specification (SRS) document containing detailed requirement capture and analysis including functional requirement, data flow, workflow based on the BPR report, interface specifications, application security requirements.

- Software Design document including Software Architecture design, Logical and Physical Database Design, Programming Logic, Workflows etc.
- Software Testing Documentation (including details of defects/bugs/errors and their resolution)
- Test Plans and Test cases (including Unit Test Plan, System/Integration Test Plan)
- User Acceptance Test Plan, Security Test Plan, Load Test Plan
- Integration Plan with other applications
- Integration Test cases & results for applications developed
- Complete Source Code with documentation post go-live.
- Complete Source Code with documentation at every 6 months during O & M Phase
- Inspection and testing procedures manual including QA Policy as per EQDC Test Plans and Test cases (Functional testing, Volume testing, Stress/Load testing, Performance testing) and report of Security testing
- Details study report for the requirement of central side IT Infrastructure based on the application developed.
- Security Level Design Document & implementation of Security policy
- Training Manuals and literature
- Systems Administration Manuals
- User manuals (English and Gujarati)
- Video Guide
- Installation Manuals
- Operational Manuals
- Maintenance Manuals
- Periodic Status and Review Reports
- Escalation Mechanism
- FAQ Concern Stakeholder
- Exit Management Plan

### 3.8 Timeline and Payment Terms:

#### 3.8.1 Proposed timelines for implementation

##### Phase 1 – Core LIMS implementation

Sr. No.	Project Activity	Timelines
1.	Signing Contract & completion of other formalities (within 15 days from the issuance of Work order)	T
2.	Project Initiation and Team Mobilization	T + 7 Days
3.	Submission of SRS Document and Wireframes	T1 = T+ 2 Months

	(Mockup screens) for LIMS	
4.	Design, Develop, Test and Implementation of LIMS	T2 = T1+3 Months
5.	UAT Completion	T3 = T2+1 Months
6.	LIMS application Testing completion through EQDC and Security audit of the application through CERT-In empaneled agency	T4 = T3+1 Months
7.	Go-Live (Design, Develop, Test, Implement, deploy at SDC and Train for LIMS portal to FDL staff)	T5= T4+15 Days
8.	LIMS Operation and Maintenance support for 5 years	5 Years from the date of Go-live

### Phase 2 – ERP Module implementation

Sr. No.	Project Activity	Timelines
1.	Phase 2 Kickoff	T5 + 15 days (from the date of Go-live of LIMS)
2.	Submission of SRS Document and Wireframes (Mockup screens) for ERP Modules	T6 = T5+ 2 Months
3.	Design, Develop, Test and Implementation of ERP Modules	T7 = T6+3 Months
4.	UAT Completion	T8 = T7+1 Months
5.	ERP Modules application Testing completion through EQDC and Security audit of the application through CERT-In empaneled agency	T9 = T8+1 Months
6.	Go-Live (Design, Develop, Test, Implement, deploy at SDC and Train for ERP Modules application to FDL staff)	T10= T9+15 Days
7.	ERP Modules application operation and Maintenance support for 5 years	5 Years from the date of Go-live

### 3.9 Payment Schedule

#### Phase 1 – Core LIMS implementation

Sr. NO.	Activity/Milestone	Payment terms
1	Submission of SRS Document and Wireframes (Mockup screens) for LIMS	10% Financial Bid Line Item 1
2	UAT Completion	20% Financial Bid Line Item 1

Sr. NO.	Activity/Milestone	Payment terms
3	LIMS application Testing completion through EQDC and Security audit of the application through CERT-In empaneled agency	40% Financial Bid Line Item 1
4	Go-Live (Design, Develop, Test, Implement, deploy at SDC and Train for LIMS portal to FDL staff)	30% Financial Bid Line Item 1
5	License cost of the Software products like OS, Database or any other third-party software required to run the application for 5 years	Financial Bid Line Item 2 50% on delivery of the licenses (to be delivered before one month on actual go-live or as may be decided mutually)  50% on go-live of the application.
6	ATS/AMC of Software products like OS, Database or any other third party software required to run the application for 5 years	Financial Bid Line Item 3  Payment will be released yearly.  (After the submission of confirmation regarding the renewal of support/subscription.)  It will be payable after Go live of the project yearly from the date of go-live.
7	LIMS Operation and Maintenance support for 5 years	Financial Bid Line Item 4  Payment will be released on quarterly basis for each year.

### Phase 2 – ERP Module implementation

Sr. NO.	Activity/Milestone	Payment terms
1	Submission of SRS Document and Wireframes (Mockup screens) for ERP Modules	10% Financial Bid Line Item 5
2	UAT Completion	20% Financial Bid Line Item 5
3	ERP Modules application Testing completion through EQDC and Security audit of the application through CERT-In empaneled agency	40% Financial Bid Line Item 5

Sr. NO.	Activity/Milestone	Payment terms
4	Go-Live (Design, Develop, Test, Implement, deploy at SDC and Train for ERP Modules application to FDL staff)	30% Financial Bid Line Item 5
5	License cost of the Software products like OS, Database or any other third-party software required to run the application for 5 years	Financial Bid Line Item 6 50% on delivery of the licenses (to be delivered before one month on actual go-live or as may be decided mutually)  50% on go-live of the application.
6	ATS/AMC of Software products like OS, Database or any other third party software required to run the application for 5 years	Financial Bid Line Item 7  Payment will be released yearly.  (After the submission of confirmation regarding the renewal of support/subscription.)  It will be payable after Go live of the project yearly from the date of go-live.
7	ERP Modules application operation and Maintenance support for 5 years	Financial Bid Line Item 8  Payment will be released on quarterly basis for each year.

### 3.10 Payment Procedure

- 3.10.1** The FDL shall certify actual implementation. The SI has to ensure proper support of the system.
- 3.10.2** SI shall raise the component wise invoice as per the milestones achieved as mentioned above in the payment schedule & submit the invoice to FDL.
- 3.10.3** FDL shall verify the invoice raised against the milestone achieved & shall make the payment after deduction of penalty, if any.
- 3.10.4** The SI's request(s) for payment shall be made to FDL along with the 2 original copies of invoice and necessary documents. The invoice should be in English language and Gujarat based.
- 3.10.5** Payment shall be made in Indian Rupees. While making payment, necessary income tax and service tax deductions will be made.



### **3.11 Delays in the Supplier's Performance**

**3.11.1** Delivery of the Goods and performance of the Services shall be made by the Supplier in accordance with the time schedule specified by FDL.

**3.11.2** If at any time during performance of the contract, the supplier or his sub-contractor(s) should encounter conditions impeding timely delivery of the goods and performance of services, the supplier shall promptly notify FDL in writing of the fact of the delay, its likely duration and its cause(s). As soon as practicable after receipt of the supplier's notice, FDL shall evaluate the situation and may, at its discretion, extend the supplier's time for performance with or without a penalty, in which case the extension shall be ratified by the parties by amendment of the Contract.

**3.11.3** As this is a service based program the delivery of hardware will be required at the time of deployment.

## **4 SECTION- IV: Service level Agreement and Penalty Clause**

The purpose of this Service Level Agreement (hereinafter referred to as SLA) is to clearly define the levels of service which shall be provided by the SI to FDL for the duration of the contract for providing FDL Applications, Training, Maintenance and Warranty support against the stated scope of work. FDL shall regularly review the performance of the services being provided by the SI and the effectiveness of this SLA.

### **4.1 Definitions**

For purposes of this Service Level Agreement, the definitions and terms as specified in the contract along with the following terms shall have the meanings as set forth below:

- "Uptime" shall mean the time period for which the specified services / components with specified technical and service standards are available to FDL and users. Uptime, in percentage, of any Central IT component can be calculated as:

$$\text{(Uptime \% = (uptime) / (Total Time – Maintenance Time) * 100)}$$

- "Downtime" shall mean the time period for which the specified services / components with specified technical and service standards as per SLAs are not available to FDL and users and excludes the scheduled outages planned in advance for the FDL central IT infrastructure.
- "Incident" refers to any event / abnormalities in the functioning of FDL specified services that may lead to disruption in normal operations of FDL services.
- "Response Time" shall mean the time taken (after the incident has been reported at the concerned reporting center), in resolving (diagnosing, troubleshooting and fixing) or escalating to (the second level, getting the confirmatory details about the same and conveying the same to the end user), the services related troubles during the first level escalation.

- The resolution time: the resolution time is the time taken for resolution of the problem and this includes provisioning of the work around to immediately recover the situation. The resolution time shall vary based on the severity of the incident reported.

**4.2 Categories of SLAs**

This SLA document provides for minimum level of services required as per contractual obligations based on performance indicators and measurements thereof. The SI shall ensure provisioning of all required services while monitoring the performance of the same to effectively comply with the performance levels. The services provided by the SI shall be reviewed by FDL against this SLA. The SI shall:

- Discuss escalated problems, new issues and matters still outstanding for resolution.
- Review of statistics related to rectification of outstanding faults and agreed changes.
- Obtain suggestions for changes to improve the service levels.

The following measurements and targets shall be used to track and report performance on a regular basis. The targets shown in the following table are applicable for the duration of the contract.

**4.3 Implementation related penalty of service levels**

a) Implementation related penalty for Application software

These SLAs shall be strictly imposed and a software audit/certification shall be carried out at the sole discretion of FDL for certifying the performance of the applications against the target performance metrics as outlined in the table below:

Milestone	Target	Severity	Penalty
As mentioned in Timeline	As per delivery Schedule	Critical	A Penalty of 0.5% of contract value of Software Application per week delay subject to maximum 10%.

Note: If the bidder is not adhering to the individual milestones as defined in the delivery schedule, the cumulative penalty will be levied for the delayed weeks, at the sole discretion of FDL. If delay exceeds maximum delay weeks at the particular milestone, FDL may have rights to terminate the contract. In that case the Performance Bank Guarantee of the bidder will be forfeited.

The SLA applicable after the implementation shall be purely measured on the availability of the services at Central site as well as client site.

**4.4 Operational Related Penalty**

**4.4.1 For Software uptime**

Sl. No	Measurement	Target	Penalty
1.	Product Availability Downtime required for maintenance, new initiatives undertaken by SI or for Performance enhancement measures shall not be considered while calculating product availability. All major maintenance shall be carried out in a planned manner after announcing it across the platform.	>= 99.7%	INR 8, 000 for every 5 hours of downtime at a stretch or in parts on a quarterly basis. And INR 1,000 for every subsequent hour of downtime at a stretch or in parts for total down time more than 10 hours on a quarterly basis.

#### 4.4.2 Application Performance

SLA Measure	Severity 1	Severity 2	Severity 3	Severity 4	Flat Penalty Rs.
<b>Response Time</b>	30 Min	1 Hrs	1 Hrs	2 Hrs	
<b>Resolution Time</b>	< 1Hrs	< 1.5 Hrs	<2 Hrs	<4 Hrs	NIL
	>1Hrs & < 2 Hrs	>1.5 Hrs & < 3 Hrs	>2 & < 4 Hrs	>4 Hrs & < 8Hrs	1000 Per Hrs
	Above 2 Hrs or part thereof	Above 3 Hrs	Above 4 Hrs	Above 8 Hrs	2000 Per Hrs

**Severity 1: Service is unavailable or a fatal error that makes the system unusable resulting in a direct business impact. The problem has resulted in the failure of business critical activities. Immediate action required.**

Example: Application Software related problems affecting all or most of the users e.g. FDL users are unable to log-in, MIS reports cannot be seen.

**Severity 2: Service is adversely affected or an error that results in incorrect outputs leading to a major function being unusable resulting in indirect business impact but whose impact is localized and not system – wide. Immediate action is needed.**

Example: End users are not able to do the entry on the form etc.; Managers are not able to check and verify details etc.

**Severity 3: Service is adversely affected resulting in limited business impact or an error that makes a minor function unusable but which can be tolerated and is to be resolved as soon as possible.**

Example: Some of the advance services such as detailed and complex reports are not available.

**Severity 4: Service is not affected.**

Example: Slow response of the system to user requests, minor suggestions and modifications in system functionality.

**4.4.3 Penalty Calculations**

- Penalty calculations shall be calculated on accumulated non-compliance for all of the above SLAs.
- Total Time shall be measured on 24\*7 basis.
- Any planned downtime for maintenance shall be with prior written permission from FDL and must be intimated to all users

Any availability/uptime requirements under SLA shall be subject to standard downtime, the time lost due to any of the following reasons are taken into account while calculating the availability/ uptime requirement:

- Time lost due to power or environmental failures;
- Time taken to recover the system because of power or environmental failures;
- Time taken for scheduled maintenance/ troubleshooting either for preventive purposes or improvement in function or other purposes;
- Time taken for reconfiguration or other planned downtime situations;
- Scheduled shutdowns as required by Department

The overall penalty cap during the contract period shall be capped at 10% of quarterly invoice value. However if such value of 10% is reached for any three consecutive months during the contract period, then the FDL will have the right to terminate the contract.

**4.4.4 Development/Change during O & M Period**

SLA Measure	Target	Flat Penalty (Rs.)
Response Time	1 Day	--
Resolution Time	Upon Mutually agreed time	NIL
	> 1 Day < 7 Days	Rs.500/- per day
	> 7 days	Rs.1000/- per day

**4.4.5 Operational Related Penalty for Development/Change during O & M Period**

Once the change is developed and implemented, it will become the part of the Software application and the operation related penalty of the application software will be applicable on that, if any.

**4.4.6 Operational Related Penalty for O & M Support**

SLA Measure	Target	Flat Penalty Rs.
Absence of Manpower and not made alternate arrangement	> 1 day	500 per day per person
Not recruited/deployed manpower	> 7 days to <15 days	500 per day per person
	>15 days	1000 per day per person

**4.5 Termination for Default or Otherwise**

**4.5.1** GIL/FDL may, without prejudice to any other remedy for breach of contract, by written notice of default sent to the Service Provider, terminate the Contract in whole or part:

- If the Service Provider fails to deliver any or all of the Goods/Services within the period(s)/schedule specified in the Contract,
- If the Service Provider fails to perform as per the performance standards.
- If the Service Provider, in the judgment of GIL/FDL has engaged in corrupt or fraudulent practices in competing for or in executing the Contract.

**4.5.2** In Circumstances mentioned in 3.13.1 above FDL may exercise the following option: -

- Direct the agency to leave the Hardware/Software and furniture in the offices of the FDL officer and terminate the Contract.

**4.5.3** In case of premature termination of Contract for no fault of Supplier FDL may exercise the following options:-

- Direct the agency to leave the Hardware and software without any additional compensation.
- Direct the agency to leave behind the Hardware & pay him the cost of Hardware less the depreciation as per the Income Tax Act / Rules. The FDL may consult GIL as to the genuine cost of Hardware. FDL may also take suitable decision as to the system/platform software in consultation with GIL.

**4.6 Force Majeure**

**4.6.1** For purposes of this clause, “Force Majeure” means an event beyond the control of the Supplier and not involving the Supplier’s fault or negligence and not foreseeable. Such events may include, but are not limited to, acts of the Purchase either in its sovereign or contractual capacity, wars or

revolutions, fires, floods, epidemics, quarantine restrictions and freight embargoes.

**4.6.2** If a force Majeure situation arises, the Supplier shall promptly notify FDL in writing of such conditions and the cause thereof. Unless otherwise directed by FDL in writing, the Supplier shall continue to perform its obligations under the Contract as far as it reasonably practical, and shall seek all reasonable alternative means for performance not prevented by the Force Majeure.

#### **4.7 Transportation**

**4.7.1** Where the Supplier is required under the contract to transport the goods to a specified place of destination within India or Gujarat defined as project site, transport to such place of destination in India or Gujarat including insurance, as shall be specified in the Contract, shall be arranged by the supplier, and the related cost shall be included in the contract price.

#### **4.8 Incidental Services**

The supplier is required to provide the following services, including additional services, if any.

- Performance or supervision of the on-site assembly and/or start-up of the supplied Goods;
- Furnishing of tools required for assembly and/or maintenance of the supplied Goods;
- Furnishing of detailed operations and maintenance manual for each appropriate unit of supplied Goods;

#### **4.9 Termination for Insolvency**

**4.9.1** FDL may at any time terminate the contract by giving written notice to the Supplier, if the Supplier becomes bankrupt or otherwise insolvent. In this event, termination will be without compensation to the Supplier, provided that such termination will not prejudice or affect any right of action or remedy, which has accrued or will accrue thereafter to GIL/FDL.

#### **4.10 Resolution of Disputes**

**4.10.1** The matter regarding any dispute shall first be sorted out at the level of Food and Drug Laboratory. If the dispute persists to remain unresolved then it will be entertained, heard & finalized as per the provisions of the Arbitration and Conciliation Act, 1996.

#### **4.11 Taxes and Duties**

**4.11.1** The rates quoted shall be in Indian Rupees and shall be exclusive of all taxes as applicable up to the completion of job. Any increase in the rates except taxes will not be allowed after signing the contract document.

#### **4.12 Binding Clause**

**4.12.1** All decisions taken by FDL regarding the processing of this tender and award of contract shall be final and binding on all parties concerned.

#### **4.13 Limitation of Liability**

**4.13.1** In no event shall either party be liable for any indirect, incidental, consequential, special or punitive loss or damage including but not limited to loss of profits or revenue, loss of data, even if the party shall have been advised of the possibility thereof. In any case, the aggregate liability of the bidder, whatsoever and howsoever arising, whether under the contract, tort or other legal theory, shall not exceed the total charges received as per the Contract, as of the date such liability arose, from the Purchaser, with respect to the goods or services supplied under this Agreement, which gives rise to the liability.

#### **4.14 Severability:**

**4.14.1** If any term, clause or provision of the agreement shall be judged to be invalid for any reason whatsoever such invalidity shall not affect the validity or operation of any other term, clause or provision of the agreement and such invalid term clause or provision shall be deemed to have been deleted from the agreement and if the invalid portion is such that the remainder cannot be sustained without it, both parties shall enter into discussions to find a suitable replacement to the clause that shall be legally valid.

#### **4.15 The FDL, GoG the right**

**4.15.1** To vary, modify, revise, amend or change any of the terms and conditions mentioned above; or

**4.15.2** To reject any or all the tender/s without assigning any reason whatsoever thereof or may terminate the tender process midway without assigning any reason.

**4.15.3** Decision regarding acceptance of tender by FDL will be full and final.

**4.15.4** Conditional tenders shall be summarily rejected.

**4.15.5** FDL is free to phase out the work if it feels it necessary.

### **5 SECTION V: ROLES & RESPONSIBILITIES OF STAKEHOLDERS**

It is suggested that this project would require a 2 tier structure to be followed, with FDL at the top tier being assisted by various committees. The SP would be the 2<sup>nd</sup> tier providing a complete support system for successful execution of this project. However, the final decision in this regard rests with the FDL on level of engagements for SI.

## **5.1 Food and Drug Laboratory (FDL)**

- 5.1.1** Receive and appraise proposals / suggestions from the SP and GIL for project implementation
- 5.1.2** To form Project Management Group (PMG) for monitoring the implementation program across the State.
- 5.1.3** Ensure that the SP conducts a detailed BPR exercise while developing and implementing the automated system.
- 5.1.4** Assist in Organizational capacity building.
- 5.1.5** Monitoring implementation, consolidation and approvals of AS-IS, BPR, Products, Case studies etc.
- 5.1.6** Identify the departments/districts/offices and approve the project report for taking up the for project implementation.
- 5.1.7** Define the services/modules for Pilot project implementation as prescribed in the selection criteria
- 5.1.8** To enter into necessary MoUs/agreements with SP for defining service levels for identified services, ensuring service level adherence, implementation and sustainability of the pilot project and subsequent state wide rollout.
- 5.1.9** Work as driver for policy, regulatory and other relevant changes.
- 5.1.10** Providing Financial Support as per the project requirements.
- 5.1.11** Assist in providing Infrastructure and other support to the SI
- 5.1.12** To organize for data entry of service records of all the employees
- 5.1.13** The necessary project team for co-ordination will be given by Food and Drug Laboratory.

## **5.2 SI/Bidder:**

- 5.2.1** Provide close tie-ups with all the stakeholders in the Project at all levels, including field level.
- 5.2.2** Provide commitment and support to bring-in the process changes.
- 5.2.3** Work closely with the different department officials, field agents, support agencies etc. to undertake the field work, comprehend the requirements, document the observations and redesign the processes by doing BPR of government administrative processes.
- 5.2.4** Help build capacity for the staff and executive resources at all levels, by providing necessary training and undertaking awareness campaigns. FDL and GIL would also work closely with the Service Provider for developing the software and implementing the technical solutions.
- 5.2.5** To provide services, IT resources, and capacity building for creation of ecosystem for high adaptability of backend computerization and e-Governance initiatives as per departments vision.
- 5.2.6** Coordinate and facilitate interactions between the various stakeholders.



- 5.2.7 Preparation of Project Framework, including aspects like scalability, security, manageability and integration features.
- 5.2.8 Submit suggestions on Business Process Reengineering (BPR).
- 5.2.9 Carrying out the field study in order to understand the requirements of the citizens, existing delivery mechanism, levels of interfaces with the Governments, the impediments and difficulties in accessing the services and information.
- 5.2.10 Designing an efficient and effective end to end service delivery process.
- 5.2.11 Understanding the capacity building requirements and help create a facility for development of capacity.

For additional Details on the Roles and Responsibility of the SP please refer to Scope of work of RFP.

## **6 SECTION VI: Specifications**

The primary goal of Testing and Acceptance would be to ensure that the project meets requirements, standards, specifications and performance prescribed in the RFP document, by ensuring that the following are associated with clear, quantifiable metrics for:

- Accountability:
- Performance
- Availability
- Security
- Manageability
- Standards and Protocols

The project would be designed to meet all functional, non-functional and management requirements as mentioned in the RFP document.

For each of the project requirements, there are operational requirements, deliverables and a set of standards, wherever applicable as per the e-Governance standard published on <http://egovstandards.gov.in> or if, e-Governance standard is not available, the industries standard should be applicable.

### **6.1 Performance Criteria**

- 6.1.1 Performance would be that aspect of service, which would be measured in terms of throughput and latency. Higher throughput and lower latency values would represent good performance of a service. Throughput would represent the number of service requests served per unit time. Latency would be the round-trip time between sending a request and receiving the response.

### **6.2 Availability Criteria**

- 6.2.1 High Availability would be a key requirement. The applications must provide department officials with timely, continuous access to information 24X7. The

log files of the applications must also be able to rebound or recover from any planned or unplanned system downtime, ensuring a minimal impact on the operations. Availability would be the quality aspect of whether the service is present or ready for immediate use. Availability represents the probability that a service is available. Larger values represent that the service would always be ready to use while smaller values indicate unpredictability of whether the service will be available at a particular time. Also associated with availability is time-to-repair (TTR). TTR would represent the time it takes to repair a service that has failed.

### **6.3 Security Criteria**

**6.3.1** Security would be the aspect of the service of providing confidentiality and non-repudiation by authenticating the parties involved, encrypting messages, and providing access control. The applications can have different approaches and levels of providing security, depending on the service requester. Security requirements such as single sign on, encryption of passwords, logs and digital signature/e-sign etc. is a must.

**6.3.2** FDL's application security will be of utmost priority. The forms should be protected from improper data input, both in the user's browser and at the remote server. Databases should be secured via username/password protection and potentially sensitive information should be secured using industry-standard encryption algorithms.

### **6.4 Manageability**

**6.4.1** Manageability needs to be a crucial aspect of FDL's application. The Implementation Partner - SP has to ensure that the solution deployed has adequate monitoring and tracking features for measuring the utilization and availability of resources. This includes:

6.4.1.1 Remote Monitoring of Status and Statistics of all high-level components

6.4.1.2 Management capability to start/ stop/ restart services and systems

6.4.1.3 Auto discovery of all components manageable

6.4.1.4 Auto discovery of all other system components

6.4.1.5 Ability to track changes in configuration of the system components to help track service

6.4.1.6 System disruptions

### **6.5 Standards & Protocols**

**6.5.1** The project should be completed as per the standards and protocols applied for development, hosting and maintenance of an automated system.

**6.5.2** The software developed under this Contract shall conform to the standards and when no applicable standard is mentioned; to the authoritative standard

appropriate to the country of origin and such standards shall be the latest issued by the concerned institution.

## **6.6 Development Criteria**

The deliverable components of this RFP include:

- 6.6.1** A web-based system by which Government official can find comprehensive information about indent request, Procurement process, distributions of material etc. Development of comprehensive FDL application through Development of Web Based application which accomplishes all the tasks as mentioned in the scope of work including the DSS and MIS reports
- 6.6.2** The design, looks, and feels of the User Interface as approved by the FDL.
- 6.6.3** A relational database(s) to be used for application management, site maintenance, calendaring and activities, and related documents.
- 6.6.4** A system to control user access privileges. Granted privileges are based on roles and responsibilities including site administration and content management, calendar, activities, and document maintenance.
- 6.6.5** Monthly or on demand reports/queries showing statistics.
- 6.6.6** Monthly/Quarterly report on product up-time hosted at the Data Centre

## **6.7 Development of Application**

- 6.7.1** The Development of Application must be done as per global industry standard environment. The bidder must justify the choice of development environment. The software must be developed and hosted utilizing industry standard. The bidder must list all tools to be used to develop and maintain the software, as well as the hosting platform hardware and software.

## **6.8 Development Control**

- 6.8.1** The bidder must use all reasonable care to protect the integrity of the product during development. Use of a version and library control tool is desired. The bidder must describe the development environment to be used.

## **6.9 Project Management & Project Plan**

- 6.9.1** The bidder must provide an experienced Project Manager to oversee the development of the FDL applications and should serve as primary point of contact for the FDL. The bidder must follow an established Project Management methodology conforming to the best practices of the Project Management. The bidder must describe the methodology to be used.
- 6.9.2** During the Technical Presentation, the bidder must provide the FDL with a detailed Project Plan for the development of the FDL application. This Project Plan must include at minimum the Project Charter, a work breakdown structure showing all proposed milestones and deliverables, and a listing of all project issues and risks.

## **6.10 Status Reports**

**6.10.1** The bidder must provide weekly status reports to the FDL during the development effort. These reports must be submitted by close of business on each Monday and must reflect status against the Project Plan as of close of business on the previous Friday. Any falsification of these status reports or failure to inform the FDL of issues impacting the deliverables or timeframe of the project may result in cancellation of the contract.

## **6.11 System Defects Correction**

**6.11.1** The bidder must respond to all reports of system defects for the duration of the contract. The bidder must correct all “Critical severity” problems (system not functioning, no workaround) within 6hours; all “Medium severity” problems (system not functioning, workaround available) within two business days; all “Low severity” problems (not impacting basic functionality) within five business days.

## **6.12 Version Control & Bug Fixing**

**6.12.1** The bidder must make any modifications necessary for the duration of the contract to ensure that the system is compatible with current and supported versions and releases of the relevant operating system and other system software.

## **6.13 Hosting Criteria**

**6.13.1** The bidder must work with the FDL to provide a detailed implementation plan, including but not limited to, orderly process of inventory, version control, and load all application materials, assignment of user rights and security, and verification of correct functionality. The bidder must present an implementation plan to the FDL for their approval by the beginning of the test period.

It is proposed that the product would be hosted in State Data Center, as per provisions provided by Department of Science & Technology, Gujarat; however the final decision regarding the primary site for hosting would rest entirely with the FDL.

## **6.14 Availability**

**6.14.1** The product must be available as per the Service levels defined. The bidder must state how that availability is to be provided, including all measures. The bidder must show the ability to report availability to FDL on a quarterly basis, and must indicate how availability is to be verified.

## **6.15 Accessibility**

**6.15.1** The FDL applications must meet the standards for software application. The bidder must test the applications with a commercially available accessibility monitor, and with a leading accessibility tool, if necessary.

## **6.16 Security**

**6.16.1** The bidder must take rigorous provisions to prevent unauthorized alteration or damage to the software and all related modules and databases. The bidder must describe in detail all measures to be taken, including the use of firewalls, monitoring for intrusion detection, etc. The bidder must also specify the dependencies, if any, in achieving the desired level of security.

(NOTE: This information will be kept confidential.)

## **6.17 Backup & Recovery**

**6.17.1** The bidder must provide and successfully test backup and recovery capabilities for the applications and related databases. The bidder must describe this functionality, and the frequency of backup.

## **6.18 Uptime & Performance**

**6.18.1** The bidder must provide sufficient provisions to ensure that product's all functionality, including data access, file downloads, and online transactions is performed within commercially acceptable response times. The bidder must state the capacity that will be available for the applications, and what tools and techniques will be used to continuously monitor application performance.

## **6.19 Access Control and User Authentication:**

**6.19.1** The bidder must prepare the access control & User Authentication policy and get it approved by FDL. The bidder shall be responsible to provide access control & User Authentication management during the period of contract.

## **7 SECTION VII: SPECIAL CONDITIONS OF CONTRACT**

The following Special Conditions of Contract shall supplement the General Conditions of Contract. Whenever there is a conflict, the provisions herein shall prevail over those in the General Conditions of Contract.

### **7.1 Service Provider's Integrity**

**7.1.1** The Service Provider is responsible for and obliged to conduct all contracted activities as defined in the scope of work in accordance with the Contract.

### **7.2 Service Provider's Obligations**

**7.2.1** The Service Provider is obliged to work closely with FDL's staff, act within its own authority and abide by directives issued by FDL

**7.2.2** The Service Provider will abide by the job safety measures prevalent in India and will free FDL from all demands or responsibilities arising from accidents or loss of life the cause of which is the Service Provider's negligence. The Service Provider will pay all indemnities arising from such incidents and will not hold FDL responsible or obligated.

**7.2.3** The Service Provider is responsible for managing the activities of its personnel and will hold itself responsible for any misdemeanor.

**7.2.4** The Service Provider will treat as confidential all data and information about FDL, obtained in the execution of his responsibilities, in strict confidence and will not reveal such information to any other party without the prior written approval of FDL

### **7.3 Acceptance Testing and Certification**

**7.3.1** As part of Acceptance testing, performed through a third party agency, FDL shall review all aspects of project development and implementation covering software, hardware and networking including the processes relating to the design of solution architecture, design of systems and sub-systems, coding, testing, business process description, documentation, version control, change management, security, service oriented architecture, performance in relation to defined requirements, interoperability, scalability, availability and compliance with all the technical and functional requirements of the RFP and the agreement.

**7.3.2** As per the Science & Technology Department, Government of Gujarat Circular No. MIS/205/2670/IT dated 10th March, 2006; every application should be tested by EQDC at Bidder cost before its deployment.

**7.3.3** FDL will establish appropriate processes for notifying the selected vendor of any shortcomings from defined requirements at the earliest instance after noticing the same to enable the selected vendor to take corrective action. All gaps identified shall be addressed by the vendor immediately prior to Go-live

of the solution. It is the responsibility of the selected Bidder to take any corrective action required to remove all shortcomings, before the roll out of the project.

- 7.3.4** It is to be noted that the involvement of the third party for acceptance testing and certification, does not absolve the vendor of his responsibilities to meet all SLAs as laid out in this RFP document.
- 7.3.5** It is to be noted that: FDL may get the solution audited through a Third Party before Go-Live and periodically after Go-Live in order to ensure the success of the project. Such third-party agency for carrying out the acceptance testing and certification of the entire solution will be nominated by the FDL.
- 7.3.6** Any issues/gaps identified by the Agency, in any of the above areas, shall be addressed to the complete satisfaction of the Department.

## **8 SECTION VIII: Scope of Work**

### **8.1 About Food & Drugs Laboratory**

Food and Drugs Laboratory is situated in Vadodara, Gujarat and performs tests on Food Products, Ingredients, In-Process Samples, Food Packaging Materials for Additives, Chemical Analytes and Microorganisms and associated Environmental aspects. Food and Drugs Laboratory offers Biological Testing for Gentamicin Injectable Preparations, Gentamicin Eye or Ear Drops, Neomycin Sulfate Ointment USP, Parenteral, Pharmacopoeial Parenteral Preparations, Black Disinfectant Fluid, Ciprofloxacin Eye Drops, Diazepam Injection, Diclofenac Injection, Frusemide Injection, Norfloxacin Eye Drops, Ofloxacin Ophthalmic Solution, Ranitidine Injection, and others. It also offers Chemical Testing for Edible Oil and Fats, Food Grains Whole, Cereal & Cereal Products, Raw and Processed Fruits and Vegetables, Tea, Spices and Condiments, Whole and Powder, Chilly, Asafoetida, Cumin, Ginger Powder, Turmeric, Dhana Powder, Sugar & Sugar Products, Honey, Dairy Product and others. Food and Drugs Laboratory has been accredited with ISO/IEC 17025: 2005 by NABL.

### **8.2 Objective**

- To convert the existing desktop application to the Web application and mobile responsive with adequate Security system in place.
- To secure sampling source data by hiding the information from those carrying out the analysis to provide unbiased result.
- Ensuring application based compliance management of FDCA lab functions.
- To offer the services of LIMS in a very easy and convenient manner.
- To improve the customer and other stakeholder trust and confidence with transparent system without compromising the confidentiality requirements.
- To increase reliability of results of customer sample and government projects.

### **8.3 Overview**

#### **Phase 1- Core LIMS application**

Bidder will provide all the core functionalities of LIMS not limited to mentioned below in this phase.

- **Web portal** - Web based portal provides users access to functionality of a LIMS through a web-browser. User Dashboards are provided for monitoring and measurement of process, completed task, pending task, and work in progress.
- **User Management** - This is a core function that controls system access and permissions. System should allow creation of new user accounts and removing/locking of user accounts. System should support user management through Roles and Groups. Roles are setting which can be applied and managed across multiple user accounts. Groups can segregate visibility to a set a user account.



- **Equipment Integration** – Integration of equipment improves automation and reduces the risk of transcription errors. Data transfer between LIMS and equipment can occur through different means. In general, equipment will output data in a specific format. Integration would require mapping the relevant data to the appropriate fields within LIMS.
- Develop state of the art integrated workflow based feature-rich system accessible from latest version of major browsers from desktop and on mobile.
- The system should generate planning recommendations to ensure effective and efficient use of resources (man, machine and material).
- To ensure that evidence is created and preserved throughout the lifecycle in electronic form with full traceability.
- Ensure effective compliance to ISO and NABL system and required internal and external audit can be handled effectively under application.
- To create, maintain and improve/update the national and international standards database used for various testing.
- To develop mobile responsive version which help inspector to do routine operation on mobile i.e. photo upload from site under inspection for food and drugs collected, upload of the inspection / testing requirements template from site itself.

## **Phase 2 – ERP Module implementation**

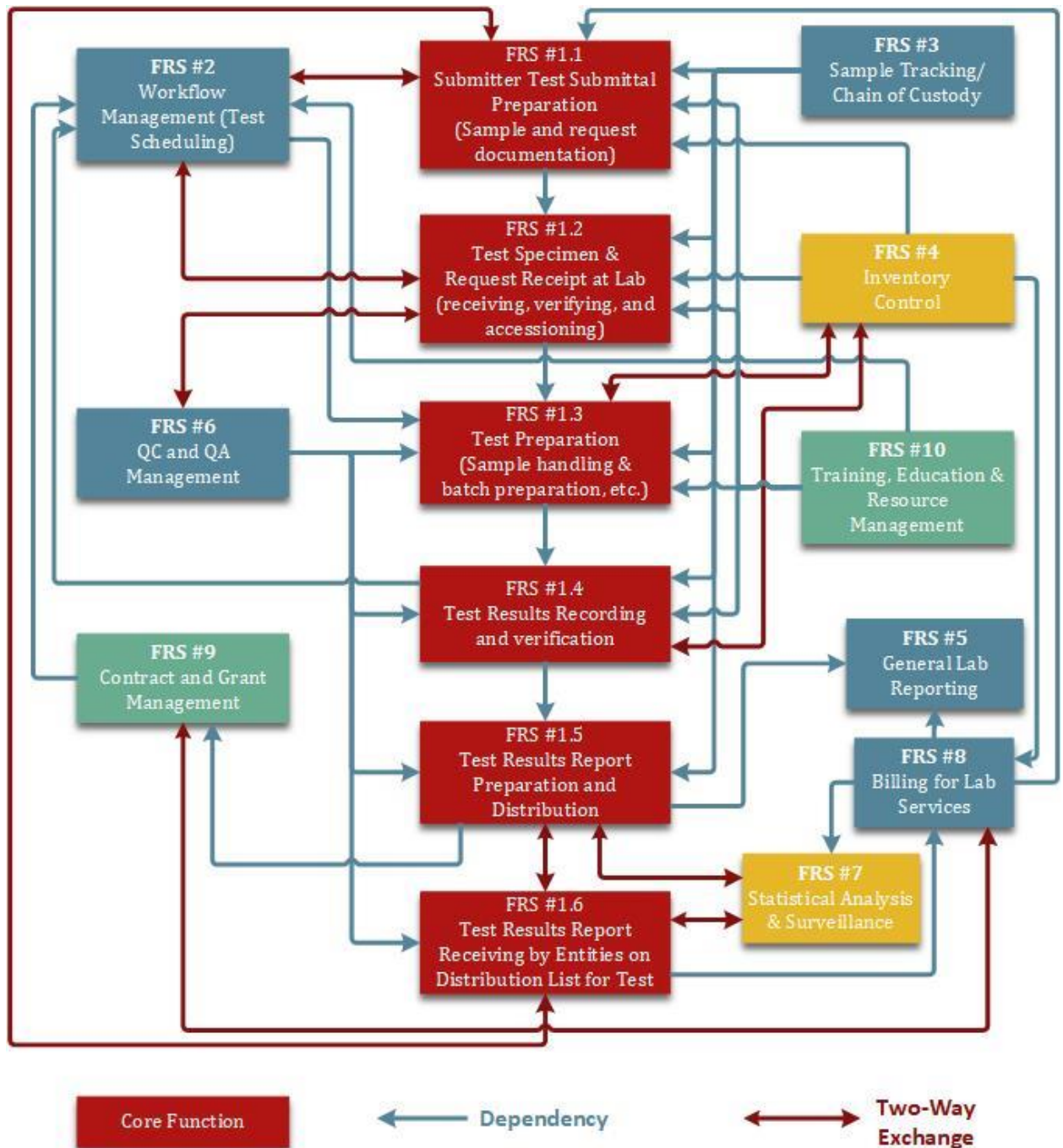
Bidder will provide following functionalities/Modules in this phase.

- IAM - Define and manage the roles and access privileges of individual users and grant/deny privileges as per requirement. Provide tools and technologies to change a user's role, track user activities, create reports on those activities, and enforce policies on an ongoing basis.
- Accounts - Financial accounting process is a central module of any ERP system. Provides financial functionality and analysis reports for ledgers, trail balance data, overall balance sheets and quarterly financial statements. Used for creating sales invoices, processing purchase invoices and creating accounting journal entries, like payment, credit and other types.
- Human Resource Management System - includes Personnel Information Management, Payroll, Leave, Time and Attendance, Shift Management, Training, Recruitment and Appraisal.
- Asset Management - Maintain fixed asset records like Building, Computers, Furniture, Cars, etc. and manage their depreciations, sale or disposal. Allows keeping

records of the employees to whom the asset has been assigned. Also, manage maintenance details of the assets with required insurance compliance management. System is expected to generate maintenance and calibration schedules for different machines/equipment to effectively manage MRO operations.

- Customer Relationship Management - Track business Opportunities from Leads and Customers, send them Quotations and make confirmed Sales Orders.
- Information sharing among laboratory's employees.

#### 8.4 Functional Requirement



**Diagram: LIMS Workflow**

## **Phase 1- Core LIMS application**

The following are drafted as functional requirements that the LIMS would have in terms of implementation in FDCA, so that the one LIMS could handle all tests that the laboratories offer to perform.

Each of the functional requirements represents a business process but not necessarily a technical specification, which will be completed by the implementer based on the functional requirements.

### **FR #1 Test Processing**

Securely deliver correct and complete test result reports to the submitting customer and other mandated recipients. Test Processing is the core activity of any Lab. This functional requirement encompasses the core work in general that reflects core laboratory workflow of laboratories at FDCA: receiving, initial processing, analytical laboratory testing, and test result reporting for specimens and samples.

Receiving includes verifying the completeness of the test request information, ensuring the adequacy/ appropriateness of the specimens/samples for testing, initial processing, and prioritizing the tests for the various internal laboratories. Test requests can be received by phone, FAX, hard copy, etc.

Testing task includes all analytical activities associated with the requested tests and recording of results. Test result reporting includes verification and secure transmission of reports via hard copy, phone, FAX, electronic copy, etc., to the customer and other mandated recipients, as well as posting results where they can be retrieved by authorized parties.

### **FR #2 Workflow Management (Test Scheduling)**

Test Scheduling optimizes the use of laboratory personnel and instruments in order to maximize the use of resources available to the laboratory and be able to adapt to sudden surges in a specific test request volume and be able to set up (define) new tests. Workflow management allows scheduling, allocation and re-allocation of work to lab technicians.

Scheduling factors include “rush” test requests, the length of time a test takes, and holding/storage time requirements. In general, test requests are processed in the order in which they are received except during an event prioritization, such as outbreak investigations.

### **FR #3 Sample Tracking/Chain of Custody**

Safe and secure sample handling through lifecycle of sample (from receiving to report generation) and create accurate and timely specimen and sample tracking and chain of custody documentation.

Specimens and samples must be tracked from the time of receipt until disposal. Besides the sequential processing from receiving through testing, specimens and samples may spend time in intermediate storage, as well as be stored for subsequent testing following the initial testing or stored as evidence.

Samples are given a system generated unique ID for traceability which is used throughout the lifecycle of the sample. Users should only be able to track samples by unique ID to maintain secrecy of source of sample to avoid any malpractice. Additional details of the sample may also be recorded as part of sample management such as time and date received, testing required, storage conditions, hazard information, expected turnaround times and current status.

In instances where chain of custody documentation is required, the lab must be able to document custody of the specimen or sample from receipt through disposal or return to the submitter or other agency. In many instances this requires a written signature or a digital signature from the custodian of the sample/specimen.

#### **FR#4 Inventory Control**

This covers all aspects of inventory control and management (ordering, tracking, and distribution) for all items inventoried by a lab such as specimen and sample collection kits, testing kits, lab supplies, chemicals, equipment (except IT equipment), and forms. Collection and testing kits management includes assembled kit inventory tracking including lot number and expiration date tracking for QC purposes. Also support stores related transactions such as stock availability, replenishment and procurement viz. RFQs, purchase order, etc. Forms management encompasses version control, printing, and distributions are included as well.

#### **FR #5 General Laboratory Reporting**

Create timely and efficient general laboratory reports addressing all FDCA's external obligations and internal management needs. A lab may have a wide variety of external reporting requirements dictated by a wide variety of organizations (Health Department, State/Central Government, test submitters, etc.), as well as internal reporting requirements that include both management reporting and records management.

End document provided to a customer is important to get right and data displayed accurately. LIMS should provide enough flexibility to customize the layout and contents. Advanced reporting functionality should allow creating own queries and format reports as per requirement.

## **FR #6 Quality Control (QC) and Quality Assurance (QA) Management**

Provide appropriate QC and QA services to ensure lab utilizing QC and QA management methodology. Although many of these activities are woven into the performance of the laboratory testing process, the determination of the QC and QA activities to be performed, the performance tracking, and the subsequent reporting requirements are management responsibilities and, consequently, are defined as a separate business process under this heading. QA not only includes internal performance, but also relates to customer performance in meeting the requirements for proper test submittal and customer satisfaction with the lab's performance.

## **FR #7: Statistical Analysis and Surveillance**

Create appropriate statistical analysis, surveillance outputs, and reports needed internally and supplied to external partners for statistical and surveillance purposes. Because of the unique laboratory role in modifiable diseases reporting (including animal diseases) and laboratories' special relationship with epidemiology (for example, helping identify, understand and control disease outbreaks), laboratories must be able to perform statistical analysis and surveillance activities. This requirement covers serving the data needs of a variety of organizations, public health agencies, other laboratories, practitioners, etc., in order to identify trends and sentinel events indicating emerging health problems, as well as actively participating in mitigation of adverse health events once they have been identified.

## **Functional Requirement - Phase 2 – ERP Module implementation**

### **FR #8 Billing for Laboratory Services**

A laboratory may engage in a wide variety of billing activities associated with the provision of lab services. These include collecting fees prior to, as well as after, the performance of lab tests and withholding lab test results until fees have been paid in certain instances, provision of indirect billing services for the laboratory and billing customers under contract arrangements for testing and training services.

### **FR #9 Contracts and Grant Management**

Accurately manage contracts and grants per agreement requirements. A given customer may have multiple contracts with the laboratory at the same time or over a period of time. Laboratory may perform testing services under a grant mechanism in which there is an agreed amount of testing to be performed.

### **FR #10 Training Education and Resource Management**

Provide appropriate staff and customer training and education, and manage overall personnel resources. This requirement includes staff and customer (if any) training and education activities, as well as the overall management of the FDCA laboratory personnel resources (including date of employment, education, certifications, etc.).

## 8.5 Detailed Functional Specification - Phase 1- Core LIMS application

### Phase 1- Core LIMS application

#### **Specifications for FR #1: Laboratory Test Processing**

This process has been broken into six internal segments as reflected in Workflow Diagram above. Only 4 out of the 6 segments need to be defined:

FR #1.2 – Test Request and Samples Receiving

FR #1.3 – Test Preparation

FR #1.4 – Testing, Results Recording and Verification

FR #1.5 – Test Result Report Preparation and Distribution

#### **FR #1.2: Test Request and Samples Receiving**

**Overview:** This segment of test processing deals with test request and specimen/sample receipt and initial processing activities. Once this work is completed, the specimen/sample will have been routed to the specific laboratory and the test request entered in the LIMS. Any problems with test submittals will have been identified and the submitter will be notified. There should be a different interface for each of human, animal, food, and plant specimens/samples workflow. Specimens/samples may also come in batch from research project or other programs.

**Workflow summary:** Receive and enter the test requests into the LIMS, check specimens/samples for completeness and acceptability, accession specimens/samples, and route to appropriate laboratories.

#### **Laboratory specific requirements for each workflow area:**

1. Receive and log test requests received in electronic message structure utilizing agreed upon coding standards with other electronic systems
  - 1.1. Ability to create test request records in the LIMS directly from the electronic test request records, (this refers to the ability to parse a test request record), and including specimen package contents (e.g., group electronic test request submittals by physical specimen package where a package may contain multiple specimens for multiple subjects)
  - 1.2. Ability to audit electronic test request records and return acknowledgement (ACK) messages to submitter verifying receipt and processing of the transmission
  - 1.3. Ability to manually enter test request if received on paper form and perform independent verification on selected data fields by re-entry of the data in a second pass
  - 1.4. Ability to handle different test request information content for human versus animal versus other miscellaneous specimen/samples (food and plant) and

identify each request record as to whether it is an outbreak, clinical, environmental or other test request in the LIMS.

- 1.5. Ability to accept and process additional epidemiology data associated with test requests from selected submitters (e.g., supplemental data segments)
  - 1.6. Ability for the user to define and create supplemental data segments and specify usage by selected submitters (e.g., a food sample testing contract may call for the collection of additional specified data only relevant to the specific food safety study under the contract and agreement)
  - 1.7. Ability to enter request forms with multiple test requests
  - 1.8. Ability to enter multiple request forms from the same submitter as a batch; without repeating entry of common data
  - 1.9. Ability to record whether or not hazard screening for bio-terrorism (BT) samples (e.g. CBRN – Chemical, biological, radiological and nuclear warfare) has been done before receipt by laboratory
2. Link specimens/samples to corresponding test requests and verify completeness
    - 2.1. Ability to link specimens/samples to corresponding electronic test request records via a LIMS display of unprocessed test requests for a given submitter, submittal date, and package ID
    - 2.2. Ability to record any specimen/sample problems that prevent testing to proceed (may happen at any point in the testing process)
    - 2.3. Ability to send electronic error messages to a submitter from other electronic systems delineating which test request(s) have been rejected, and generate these messages automatically for all errors associated with a specific package once problems have been recorded in LIMS
3. Accession specimens/samples
    - 3.1. Ability to accession specimens/samples with individual laboratory specific unique numbers using a common accessioning protocol that allows real-time tracking of specimen progeny and siblings
    - 3.2. Ability to create specimen/sample labels
    - 3.3. Ability to create specimen/sample barcode labels using FDCA designated barcode format
    - 3.4. Ability to create post script numbers for splits and aliquots of original specimen/samples
    - 3.5. Ability to use accession number as a direct link to the corresponding LIMS test request record
    - 3.6. Ability to create skeleton test request record (test ID, accessioning number, and other core data) when total data entry might preclude timely testing
    - 3.7. Ability to flag skeleton record as incomplete and create queue of incomplete test request records needing remainder of data to be entered
  4. Route specimens/samples to appropriate laboratories
    - 4.1. Ability to update LIMS with routing information (laboratory to which a specimen sample is directed) and status code (the code will be defined by FDCA)



- 4.2. Ability to route specimens/samples associated with a test request submittal to multiple laboratories
- 4.3. Ability to route test requests to a centralized aggregation point, such as the reference laboratories, for special projects or when an event prioritization occurs.
- 4.4. Ability to create supporting documentation and packaging/shipping labels when routing specimens/samples to reference laboratories
- 4.5. Ability to utilize a directory or registry to hold message recipient contact and protocol information
- 4.6. Ability to modify or inactivate a test request

**Selected QC/QA specifications:**

1. Ability to capture specific data elements associated with QC/QA measures associated with this functional requirement (see Functional Requirement #6 for additional information)

**Selected system output requirements:**

1. Report of specimen/sample rejections by rejection code and submitter for user Specified time period
2. Report on tests requests forwarded to other reference laboratories
3. Report on specimens/samples splits and aliquots
4. Reports on number of specimens accessioned by site, program, etc.
5. Report of overdue specimens, including the ability for an authorized user to define when a specimen is overdue
6. Reports on test requests by submitter and timeframe

**FR #1.3: Test Preparation**

Overview: Upon receipt in the laboratory, the specimen/sample will be prepared for testing. This work includes creating any desired aliquots, any preliminary processing completed, and batch runs created where appropriate.

Workflow summary: Test preparation preliminary processing and batch run creation

**Laboratory specific requirements for each workflow area:**

1. Test preparation and preliminary processing
  - 1.1. Ability to create additional post scripted accessioning numbers for laboratory splits and aliquots
  - 1.2. Ability to create and schedule a new test based on type of testing originally requested (a form of reflex testing)
  - 1.3. Ability to update test request status and tracking record to track splits and aliquots
  - 1.4 Ability to add additional tests to previously tested sample
2. Batch run creation
  - 2.1. Ability for user to define test instrument specific uniquely defined batches based on the specific needs of the analytical area. Further:

- 2.1.1. Ability to determine position of each standard and control specimen in the batch and specify specimens/samples for duplicate testing.
- 2.1.2. Ability to track specimen/sample dilutions
- 2.1.3. Ability to specify whether test results are manually entered or will be “resulted” from an instrument. If test results are manually entered, the system should automatically call up all items on the list sequentially or the whole worksheet to be resulted at operator request.
- 2.1.4. Ability to select all pending tests for worksheet generation, select a range of pending specimen/samples, if desired, (by date range, for example) and “tag” specific tests for worksheet generation.
- 2.1.5. Ability to note specific safety concerns or hazards associated with the procedure’s performance, reagents, on each worksheet
- 2.2. Ability to create and print batch worksheet and allow user to regenerate (modify) the worksheet and add tests up to the point when the batch run results are entered.
- 2.3. Ability to prioritize test requests from test queue for inclusion in a batch.
- 2.4. Ability to display and/or print batch map (specimen/sample location by well/position).
- 2.5. Ability to create additional numerical sequence numbers and labels for consecutive specimen/sample numbering within a batch.

Selected QC/QA specifications:

1. Ability to capture specific data elements associated with QC/QA measures associated with this business process (see Functional Requirement #6 for additional information)

Selected system output requirements:

1. Report of reflux and other subsequent testing organized by source test and reason
2. Report of list of samples for retesting and reason

#### **FR #1.4: Testing, Results Recording and Verification**

Overview: This segment of the test processing encompasses the testing, QC checks for validity of the results, the recording of the test results, and the generation of additional test requests where additional testing, based on the initial test results, is needed. In addition, in the case of QC failure, retesting requests are generated.

Workflow summary: Test results reading and recording, QC verification, and creation of additional test requests

#### **Laboratory specific requirements for each workflow area:**

1. Test result recording
  - 1.1. Ability to present uniquely identified batch worksheet result entry screen in same sequence as batch
  - 1.2. Ability to allow manual entry of positive entries only and then default remainder of tests in batch to negative description
  - 1.3. Ability to select result description from user defined table for valid entries for each given test and apply the selected description to multiple tests in batch

- 1.4. Ability to enter text field comments related to entire batch with the ability to code the comment as “internal lab use only” when appropriate so it doesn’t show on reports sent outside the lab
  - 1.5. Ability to remove “obvious outliers” when applicable
  - 1.6. Ability to support complex calculations (concentration calculations, etc.)
  - 1.7. Ability to change the specimen condition in resulting (lab accident, etc.)
  - 1.8. Ability to enter text field comments related to specific test result
  - 1.9. Ability to change mistakes in data / dates / results even in final submitted version
  - 1.10. Ability to highlight positive tests so they stand out on batch presentation
  - 1.11. Ability to capture ID of laboratory technician performing the test and creating the result entries along with date and time of analysis. Methods may include biometrics, etc.
  - 1.12. Ability to allow easy recombination of individual determinations into multiple test suites (generally a tree type structure which may have multiple grouping levels)
  - 1.13. Ability to average results on duplicate specimens/samples using the intra specimen sample variation as a QC parameter and store a record of all results
  - 1.14. Ability to track specimen/sample dilution factors back to undiluted specimens/samples and select the most appropriate test result (based on per test preferred concentration ranges) and select a correction of the dilution and record a corrected result
  - 1.15. Ability to monitor for and create alerts of “major” variations from normal
2. QC verification
    - 2.1. Ability to define test (batch) specific control ranges
    - 2.2. Ability to flag batch as suspect due to QC test values
    - 2.3. Ability to reject the batch based on QC failure and create appropriate audit trail
    - 2.4. Ability to tag each test in batch with QC failure reason
    - 2.5. Ability to present peer (second reading entry or review) validation screen
    - 2.6. Ability to enter peer validation edits and changes while keeping original recorded results with full audit trail for all changes/modifications
    - 2.7. Ability to enter peer reviewer ID for each batch
    - 2.8. Ability to create queue of batch test worksheets ready for peer or supervisory review
    - 2.9. Ability to present supervisor review screen
    - 2.10. Ability to enter supervisor validation edits and changes while keeping original and peer review recorded results
    - 2.11. Ability to release test batch for result printing once all required reviews have been completed
    - 2.12. Ability for a supervisor to over-ride a batch or individual test result tagged with a QC failure and to log a comment on why it was released despite the QC failure
3. Creation of additional test requests

- 3.1. Ability to trigger retest requirement and set up the tests in the test queue
- 3.2. Ability to arbitrarily repeat any individual test request in a batch
- 3.3. Ability to reuse same accessioning number for retest run
- 3.4. Ability to link rejected test run to subsequent rerun
- 3.5. Ability to create additional test requests associated with initial test results
- 3.6. Ability to link initial test information to subsequent/additional testing

Selected QC/QA specifications:

1. Ability to capture specific data elements associated with QC/QA measures associated with this business process (see Functional Requirement #6 for additional information)

2. QC reports on what was changed, why, and by whom

Selected system output requirements:

1. Workload statistics based on provider, test result, and time frame

2. Ability to create report on pertinent run data for a specific batch including QC data associated with each test request

### **FR #1.5: Test Report Preparation and Distribution**

**Overview:** The recorded test results are used as the basis for the preparation and delivery of the test results report to the submitter and the creation and delivery of test results reports to other designated users

Workflow summary: Create and deliver hard copy or electronic test reports to submitter and other qualified users and prepare test result tabulations for other qualified users

Laboratory specific requirements for each workflow area:

1. Create and deliver test results to submitter

- 1.1. Ability to create electronic test report transactions and to transmit electronic test results either individually or by batch

- 1.2. Ability to control which results, detailed or summary, should be included in a report

- 1.3. Ability to transmit print image so that submitter can print out hard copy in the laboratory prescribed form including letterhead image

- 1.4. Ability to send a test impression summary result that is an interpretation of multiple detailed test results

- 1.5. Ability to upload pictures of other file along with the results of sample inconsistency report, such as PCR gel picture, bacteriology results, and hemolysis

- 1.6. Ability to control which results, detailed or summary, should be included in a report

- 1.7. Ability to add comments to individual and batch test in a report for electronic and hard copy

- 1.8. Ability to transmit electronic test reports in secure format (such as ebXML format utilizing Public Key Infrastructure (PKI) encryption

- 1.9. Ability to attach electronic signature to each electronic record when applicable

- 1.10. Ability to print hard copy test report for mailing containing an electronic signature (one way is to attach the printed signature field onto the test record as the

report is prepared for printing rather than having it as a standard text field in the print format)

1.11. Ability to indicate that the report is “preliminary,” “final,” “corrected,” or “amended and track multiple revisions to the same report

1.12. Ability to sort printed hard copy test results by submitter prior to printing, and print a cover sheet for each submitter grouping

1.13. Ability to create mailing labels for each submitter test report package

1.14. Ability to update test request record to indicate report has been created

1.15. Ability to create duplicate or amended test reports in either electronic or hard copy with indication that they are “duplicate” or “amended”

1.16. Ability to flag list of user-defined results requiring immediate submitter notification, including creation of call lists (submitter table will carry contact information)

1.17. Ability to record notification contact information including date and time, person notified, laboratory person making the contact, and the result(s) recorded

2. Prepare test result tabulations for other qualified users

2.1. Ability to qualify (i.e., grant permission to see) users by specific report

2.2. Ability to create and maintain authorized distribution list for each report

2.3. Ability to read a registry or directory to get contact and/or protocol information for report recipients

2.4. Ability to utilize a rules engine to determine the recipients for a message. The rules would dictate different recipients based on parameters ranging from: the type of test requested in the received test order; to the heightened urgency of the test as would be dictated during an event

2.5. Ability to tabulate test results by “positive” or total tests processed or a “rate positive” for a given geographic area by user over a specified time period through the use of a GIS tool when such a tool is available

2.6. Ability to release individual test results to a submitter prior to the completion of other related testing or recording of other test results in the same batch

### **Selected QC/QA specifications**

1. Ability to capture specific data elements associated with QC/QA measures associated with this business process (see Functional Requirement #6 for additional information)

### **Selected system output requirements: (Many of these are embedded in the above requirements specifications)**

1. Data exports to other reporting programs

2. Reports of number of tests per instrument per time period

3. Reports of number of tests performed by work unit by time period

4. Reports of number of tests by method by time period

5. Ability to create reports of tests (last three entries) for client specimen/sample tests only (i.e., exclude QC and proficiency tests)

6. Data extracts to NFA (food quality, food alterations, etc.)

7. Lab test kit performance reporting (reagent failure, performance problems, etc.)
8. Ability to create “overlays” of data from both clinical and environmental testing by geographic area
9. Reports on number of duplicate, amended, etc., reports issued

## **Specifications for FR #2: Workflow Management (Test Scheduling)**

Overview: This functional requirement deals with prioritizing and processing the test workload already received. Scheduling factors include request urgency, specimen/sample holding time, and other factors relating to the timely processing of the test requests.

Workflow summary: Add requests received, prioritize requests, and remove requests that have been completed, and publish real-time test schedule.

Specific requirements for each workflow area:

1. Add requests received or additional tests generated in-house
  - 1.1. Ability to add test requests and specimens/samples received and accepted by the lab to specific test schedule
  - 1.2. Ability to add in-house generated tests to schedule
2. Prioritize requests
  - 2.1. Ability to assign a submitter priority to a specific test
  - 2.2. Ability to assign priority by type of test
  - 2.3. Ability to generate internal priority based on holding times, number of days since receipt, and other factors associated with specimen/sample
  - 2.4. Ability to adjust priorities
  - 2.5. Ability to organize test “queue” by priority
3. Remove completed requests/transfers from active queue
  - 3.1. Ability to automatically delete tests from the schedule once the result has been entered in the LIMS (and restore if needed)
  - 3.2. Ability to manually delete a test request from the schedule/batch (and restore if needed) or delete an entire batch
  - 3.3. Ability to select tests for diversion to mutual assistance laboratory and create file of diverted tests
  - 3.4. Ability to create packing lists and other documentation for diverted tests
  - 3.5. Ability to adjust holding times based on extractions and other reasons
  - 3.6. Ability to divert specimens/samples to another area in-house based on a trigger from a completed test for subsequent testing
4. Publish real-time test schedule
  - 4.1. Ability to calculate daily processing capacity for each test; adjusted by instrument avail ability and personnel availability
  - 4.2. Ability to translate workload into N-day “rolling schedule” based on capacity limits where N is the number of days ahead of current date the user wants to include in the display
  - 4.3. Ability to track test loads in the schedule at the specific instrument level

4.4. Ability to indicate which tests have been passed through to another laboratory (mutual assistance situation, etc.)

4.5. Ability to record test results for tests performed by another laboratory and indicate name of person who performed the test

4.6. Ability to create subsequent test requests from a given test request

4.7. Ability to flag overdue test requests based on schedule and notify submitter

**Selected QA specifications:**

1. Ability to capture specific data elements associated with QA measures associated with this functional requirement (see Functional Requirement #6 for additional information)

**Selected system output requirements:**

1. Reports of test processing time by priority

2. Test status reports

**Specifications for FR #3: Specimen and Sample Tracking/Chain of Custody**

Overview: In many instances, the chain of custody documentation originates outside the laboratory and will arrive with the test specimen/sample. Once started, the chain of custody needs to be maintained so most laboratories simply continue using the manual form. However, as back up to the formal chain of custody, the LIMS contains a great deal of information about the routing of the specimen/sample through the testing process. It could also contain entries to track the specimen/sample into and out of primary storage and its ultimate disposition. Ideally, the LIMS would be able to identify the location of a specimen/sample at any step in the process, at least by storage location and device ID, if not also by the shelf and box location wherever it is stored. This would also facilitate the need to establish the link between specimen/samples and the QC documentation on storage temperature control, in that the temperature control sheets are date range-specific, and the date range for which the specimen/sample was in a given refrigerator would be captured as a part of the specimen/sample tracking transaction.

**Workflow summary:** Tracking specimens/samples, control materials and media movement into and out of storage.

Specific requirements for each workflow area:

1. Record movement of specimens/samples

1.1. Ability to record storage refrigerator or container ID, date stored, date removed for a specific specimen/sample ID

1.2. Ability to record dates and location when a specific specimen/sample was out of storage for testing process (could be linked to the test batch start and end times if recorded as a part of batch processing)

1.3. Ability to record specimen/sample disposition date and disposition code (if any)

1.4. Ability to move entire contents of a given storage location to another location (i.e., freezer mechanical failure)

1.5. Ability to make a tracking stop mandatory (i.e., a specimen must end up in a specific freezer)

1.6. Ability to identify and track individuals with specimen/sample custody

1.7. Ability to support and modify “chain of custody routing rules” by type of specimen/sample and use the rules for alerts when the actual chain of custody deviates from the standard rule set (if such rule set exist)

1.8. Ability to access threat assessment information for each specimen/sample

1.9. Ability to flag a specimen/sample with a user defined code for “legal” or other desired code  
1.10 Ability to track specimen/sample to forwarded locations and to external lab

1.10. Ability to track rejected specimen/sample

2. Capture of temperature information (less important)

2.1. Ability to manually enter header record for specific temperature sheet for a specific refrigerator and sheet begin and end dates

### **Selected QA specifications**

1. Ability to capture specific data elements associated with QA measures associated with this business process (see Functional Requirement #6 for additional information)

### **Selected system output requirements**

1. Report on a given specimen/sample’s location from receipt to disposition by location and date
2. Report on rejected specimen/sample sending to the submitter
3. Tracking reports of known specimens/samples (QC organisms, etc.)
4. Report on the contents of a given refrigerator/freezer on any given date

## **Specifications for FR #4: Inventory Control**

Overview: Based on manufacturer availability and the contractors for the Government, inventories may contain manufacture test kits, media, reagents, stains, controls, or other items (i.e., laboratory supplies) used by the laboratories for test processing. Inventory items may be ordered from manufactories and are stored at center storage and then delivered to individual laboratories.

Workflow summary: Receive and process orders, and replenish inventory

1. Test kit management (a): Kit component ordering and receiving, kit assembly, submitter order receipt and processing, and shipping.
2. Inventory control (b): Monitor inventory quantities, create replenishment orders, receive inventory and add to balances, receive and fill orders from individual laboratories.
3. Forms management (c): The management of forms versions and distribution.

Specific requirements for each workflow area

1. Receive and process orders from internal laboratories and replenishment orders from inventory control. The replenishment order may be for more plates, which would potentially cause a need for more media to be produced which would have a ripple effect back to the inventory business process.

1.1. Ability to record orders

1.2. Ability to schedule manufacturing run based on inventory counts and orders



1.3. Ability to flag minimum quantity levels for triggering of reorders

**2. Specific requirements for each kit management workflow area**

2.1. Kit component ordering and receiving

2.1.1. Ability to process proactive specimen/sample schedules and set delivery dates and inventory quantities

2.1.2. Ability to track inventory status and create replenishment orders for kit components based on assembled kit shipping schedule

2.1.3. Receive component orders and increment stock inventories

2.2. Process submitter orders

2.2.1. Ability to create order packing slips for kit shipment to specific submitter locations based on proactive specimen/sample schedule delivery dates

2.2.2. Ability to receive and process kit orders directly from submitters (lower level laboratories) either electronically or manually submitted

2.2.3. Ability to block order preparation based on submitter budget status or records indicate they have sufficient quantity on hand based on number of test requests received by the laboratory

2.2.4. Ability to create submitter test kit invoice information for prepayment or payment subsequent to shipping for processing by billing function

2.2.5. Ability to decrease inventory counts for order items pulled for shipping

2.3. Ship submitter orders

2.3.1. Ability to create order package labels and change order status for each specific submitter ship to location

2.3.2. Ability to record shipping information for tracking purposes

**3. Specific requirements for each inventory control workflow area**

3.1. Monitor inventory levels and create replenishment orders

3.1.1. Ability to monitor inventory levels and anticipated usage

3.1.2. Ability to create replenishment orders

3.2. Receive orders and stock inventory

3.2.1. Ability to update stock on hand and decrease outstanding order quantities based on quantities received

3.3. Receive and fill internal and external laboratory and media kitchen orders

3.3.1. Receive and record orders (or receive them electronically from the individual laboratories or media kitchen)

3.3.2. Ability to decrease inventory counts for order items pulled for delivery to bench or shipped to other laboratories

3.3.3. Ability to create billing invoice for external sales

3.3.4. Ability to produce physical inventory worksheets and reconcile physical inventory counts with LIMS counts

3.3.5. Ability to create inventory labels to track date received, time put in use, etc.

**4. Specific requirements for form management workflow**

4.1. Ability to electronically create and distribute new versions of forms and other documents necessary for the operation of the laboratory

4.2. Ability to manage the acquisition and distribution of forms and documents obtained in hard copy from external sources (scanned form stored in LIMS database)

4.3. Ability for users to create and modify on-line requisition form for use by the laboratories in ordering items from inventory

**Selected QC/QA specifications**

1. Ability to capture specific data elements associated with QC/QA measures associated with this specific process (see Functional Requirements #6 for additional information)

**Selected system output requirements**

1. Inventory item usage by item and cost (also person/section who used)
2. Projections of inventory item usage by user defined time period and current proactive specimen/sample collection schedule, including estimated submitter inventory levels
3. Cost history by item, cost center, and other factors
4. Documentation of manufacturer QC for applicable items
5. Report on sales to external laboratories by laboratory and item for user specified time period
6. Reports of kit shipments to submitters by submitter location and/or collector
7. Reports of test cost profiles for all items supplied to laboratories
8. Reports on kit outdating (kits in inventory that have expiration dates)

**Specifications for FR #5: General Laboratory Reporting**

General Reporting: Many of these reports support general “business management” activities that are specified in each functional requirement. Standard reports embedded in LIMS are not necessarily specified in this section, but there are some examples that may be useful when looking for general reporting.

Examples include:

1. Ability to provide Workload Reports (periodic – weekly, monthly, yearly, etc. – workload reports that will indicate separate counts of specimen/samples received and tests performed for each analytical area)
2. Ability to provide reports that differentiate between client-ordered tests and tests done in house as part of a testing protocol or study
3. Ability to provide Work Time Unit reports (reports that calculate the amount of labor it took to run the tests). The system should also be flexible enough so the laboratories can add, delete, or change tests and work time units as needed.
4. Ability to provide Quality Assurance Reports which means that the system should produce reports based on any of data fields and the comment fields where additional QA information will be stored. Examples of QA reports include information about unsatisfactory specimens/samples, specimen/sample rejection, improperly labeled specimen/samples and/or request slips, etc.
5. Ability to provide Turn-around Time Reports (reports showing the turn-around times for specific tests or test groups, including the average turn-around times plus the number that meet, exceed, and are less than predetermined turn-around times)
6. Ability to provide Quality Control Reports (reports showing periodic summaries of QC results with detailed reports of exceptions including detailed listings of QC results for a

particular date range, as well as tracking changes in QC measures and who made the changes)

7. Ability to provide Submitter Usage Reports (summarized reports providing lists of submitters and the tests they requested for a specified period of time)

### **Specifications for FR #6: Quality Control (QC) and Quality Assurance (QA) Management**

Overview: The key element for QC and QA is the ability to support an integrated view of QA/QC activities and quality measures.

1. For QC this involves the ability to determine the applicable QC elements that were operative at the time any test was performed and to be able to retrieve the documentation references through the use of the LIMS if the information is stored on hard copy. Ultimately, the goal would be to have electronic documentation complete with electronic signature capability.

2. For QA the goal is the ability to capture the data elements that define each QA measure and make it easier for the PHL to track and evaluate the QA measures. This functional requirement focuses on the overall management of the QC/QA function.

Workflow summary

1. Establish QC parameters for each test/method including manufactured or purchased ingredient used in conjunction with the test/method as well as specimen/ sample condition tracking, capture QC data for each test, and analyze trends in QC test results.

2. Establish and review each QA measure and determine data sources available for supporting each measure, capture QA measures, and analyze trends and institute corrective actions when necessary.

Specific requirements for each QC workflow area

1. Establish external quality assessment (EQA)

1.1. Ability to create and maintain a master record for test sent out for proficiency testing, rechecking retesting, and on-site evaluation with sample type, test methods, sample receiving laboratory information, time, payment information, etc. For example, FDCA reference lab sends tests to regional/private labs (customers), receives results, performs data analysis and generates final reports

1.2. Ability to create and maintain a master record for recording test results received from test sent out for proficiency testing, rechecking retesting, and on-site evaluation. For example, FDCA reference lab receives samples from abroad (international EQA providers) performs testing, sends results back to provider and receives final scores/report. If the results are not sufficient, after the management review center plans corrective actions, puts into the practice and assess their efficiency.

2. Set up each QC parameter and associated data elements

2.1. Ability to create and maintain a master record for each QC test by instrument/method.

2.2. Ability to create and maintain a master instrument/test/method records for associated input QC parameters (media, reagents, etc.).

- 2.3. Ability to create and maintain a master instrument/test/method record for specimen sample condition tracking elements (temperature control, holding time, etc.)
- 2.4. Ability to link the QC records for QC test, associated input, and specimen/sample condition if not created in same database table
- 2.5. Ability to capture SOP on each instrument/test/method along with effective dates for each version

### 3. Capture QC measures

- 3.1. Ability to electronically capture all QC measure values as appropriate as a part of the testing process
- 3.2. Ability to manually enter QC measure values in cases where the measures are not included in the testing process support (media manufacturing, etc.)
- 3.3. Ability for user to define the placement of QC and proficiency tests within a batch

### 4. Analyze QC measures

- 4.1. Ability to track QC measures and create analyses by time period or individual tests. For example, analysis capabilities might include:
  - 4.1.1. Ability to perform a variety of data reduction capabilities including linear regression (straight line fit), Log (Logit), Four Parameter Logistic and Cubic Spline.
  - 4.1.2. Ability to produce Levey-Jennings QC plots, as needed.
  - 4.1.3. Ability to use institute specific or common QC rules (such as Westgard) to evaluate whether analysis is in or out of control. The rules must be able to be turned on or off as needed for each test performed as well as specifying which rules to use for each test. The rules must be able to be used on a real time basis for problem identification.
- 4.2. Ability to analyze information on unknown specimens/samples, spiked specimens/samples and duplicate specimens/samples
- 4.3. Ability to create alerts when QC measures trend toward limits
- 4.4. Ability to warn users that QC for one or more elements for an instrument/test/method has failed under either batch or individual test circumstances
- 4.5. Ability to automatically reschedule all tests invalidated by a QC failure with manual over-ride by supervisory personnel
- 4.6. Ability to create a report of all QC measures associated with a specific specimen/sample submission
- 4.7. Ability to include electronic signatures for QC entries

### **Selected QA specifications:**

1. Set up and maintain each QA measure
  - 1.1. Ability to create and maintain master records for each QA measure
2. Capture each incidence of each QA measure
  - 2.1. Ability to electronically transfer QA data associated with other business process support files
  - 2.2. Ability to manually enter QA data not captured in the LIMS as a part of other process support
3. Analyze each QA measure and institute corrective action where necessary
  - 3.1. Ability to track QA measures and create analyses by time period
  - 3.2. Ability to create alerts when QA measures trend toward limits

3.3. Ability to trigger special reports when QA measures have exceeded acceptable limits

#### **Selected system output requirements**

1. Reports of QC failures for specified timeframe by specific laboratory, instrument, test, and method
2. QC reports for support of audit activities
3. QC analysis reports on duplicate testing
4. Reports/screen displays of standard operating procedures for each method with “read only” security controls
5. QA reports for management by QA parameter

#### **Specifications for FR #7: Statistical Analysis and Surveillance**

Overview: Laboratories are in a position to greatly “enrich” the test data that is passed on to a variety of critical users and back to the submitters. Obviously, the key deliverable is accurate and timely test results. These results represent the major objective of a laboratory’s activity and the reason for its existence. This functional requirement deals with several ways in which the laboratory can contribute to the broader public health objective of assessment, policy development, and assurance in terms of identifying and responding to adverse health events caused by disease or environmental factors in Gujarat. These contributions can be broken out into two general categories: as a conduit for surveillance data and as a contributor to the understanding of the cause and impact of adverse test result patterns.

Workflow summary: Capture and pass along non-test specific information, perform additional testing for typing and understanding primary results, and perform statistical analysis activities intended to identify suspicious test request and result patterns

#### **Specific requirements for each workflow area**

1. Provide a conduit for non-test specific data associated with test request submittals
  - 1.1. Ability to electronically transmit non-test data elements to specified users
  - 1.2. Ability to electronically or manually capture and store the non-test specific data
  
2. Perform additional testing for typing and understanding of primary results
  - 2.1. Ability to flag test results for which subsequent testing would be appropriate and automatically add follow up test requests to testing schedule
  - 2.2. Ability to link the subsequent test results to the primary test report
  - 2.3. Ability to build business rule tables for use in flagging described above (2.1)
  
3. Analyze test result patterns
  - 3.1. Ability to create positive test results as rates (positives related to total submittals)
  - 3.2. Ability to analyze positive test patterns by type of test
  - 3.3. Ability to present combinations of clinic and environmental tests by geographic location for clustering analysis
  - 3.4. Ability to create user defined extracts of test data for electronic transmittal to specified users utilizing a standard open file structure format such as comma delimited flat files

**Selected QA specifications:**

1. Ability to capture specific data elements associated with QA measures associated with this business process (see Functional Requirement #6 for additional information)

**Selected system output requirements:**

1. Ability to enable the laboratory to send certain specified test results to users (such as Epidemiology) other than the submitter before being sent to the submitter.

**Phase 2 – ERP Module implementation****Specifications for FR #8: Billing for Laboratory Services**

Overview: FDCA may engage in a wide variety of billing activities designed to help offset the testing costs. In general, the billing is associated with the following aspects of the laboratory's workflow: provision of collection kits and containers to submitters, testing and test reporting, provision of training services, and laboratory annual licensing fees and inspection services.

Workflow summary: The work involves obtaining the billing information from the submitter or other entities, tabulating the items to be billed, applying appropriate billing rates, and creating the invoices and supporting billing documentation.

Specific requirements for each workflow area

1. Obtaining submitter and other entity billing information
  - 1.1. Ability to capture and maintain submitter billing address and responsible party information
  - 1.2. Ability to specify which services are included under a given contract agreement and tag each service with an active/inactive flag (or timestamp each unique set of services active under the agreement for any given service provision date)
  - 1.3. Ability to capture and maintain agreed upon charges for specific services if different than standard billing rates
2. Identification of services performed and qualifying for billing
  - 2.1. Ability to match services provided against the submitter billing master for creation of billing ledger entries (i.e., selection of billable services from the LIMS records indicating the provision of the services)
  - 2.2. Ability to allow for costing and fee development at either the instrument test level or test/method level.
3. Preparation of invoices and billing documentation
  - 3.1. Ability for user to select specific billing ledger entries and create submitter specific billing invoices
  - 3.2. Ability to create hard copy invoices grouped by submitter
  - 3.3. Ability to create electronic billing invoices in lieu of paper
  - 3.4. Ability to track billing and payment status
  - 3.5. Ability to create billing invoices for services requiring prepayment that are linked to a submitter's purchase order or request for the services

- 3.6. Ability to block shipment of kits and other items if prepayment is required
- 3.7. Ability to collect payments (including cash payments), print receipts, and account for miscellaneous prepaid service requests (walk-in business for well water testing from the public, if applicable, for example)
- 3.8. Ability to create preliminary bill with initial test results

**Selected QA specifications:**

1. Ability to capture specific data elements associated with QA measures associated with this business process (see Functional Requirement #6 for additional information)

**Selected additional system output requirements:**

1. Ability to create billing reports by submitter, timeframe, service and other key parameters
2. Ability to track grant & contract services and associated fees
3. Ability to create reports for non-billable services indicating cash value by grant/contract based on standard costs
4. Ability to report on test billing – what tests have been billed and the amount billed by selected time period

### **Specifications for FR #9: Contract and Grant Management**

Overview: Contracts and grants between FDCA and State Government or with other institutes and users of the laboratory services may involving specific services requests (generally clinical from hospital or food safety testing) by type and quantity. Contract/grant limits may be stated in either number of tests to be performed or total rupees. The key aspect of contract and grant management in LIMS is the tracking and reporting of the services provided to the users to ensure that the laboratory has met the conditions of the agreement in terms of the services provided and the timeframe in which they were provided. Some agreements also contain schedules for the timing of test requests over the life of the agreement.

Workflow summary: The workflow includes creating the anticipated test request schedule, ensuring that all collection kits required are delivered in a timely manner to the submitter(s), tracking of tests performed under the agreement (both dollars and numbers), and providing periodic updates of services performed under the agreement.

Specific requirements for each workflow area:

1. Contract/grant set up
  - 1.1. Ability to create tracking file containing grantor name and address information, time period, tests covered, and specimen/sample collection schedules
  - 1.2. Ability to create collection/collector name and address information associated with each contract/grant and link to collection schedule
  - 1.3. Ability to record and track contract/grant objectives and their achievement
2. Tracking tests performed
  - 2.1. Ability to track tests performed under each contract by collector within each grantee contract

3. Periodic reporting on contract/grant status
  - 3.1. Ability to alert test scheduling when contract/grant service limits have been or are close to being reached.
  - 3.2. Grant reporting tickler file (due dates and responsible party in FDCA)

#### **Selected QA specifications**

1. Ability to capture specific data elements associated with QA measures associated with this business process (see Functional Requirement #6 for additional information)

#### **Selected system output requirements**

1. Reports by contract/grant showing testing schedule, tests performed to date, and rupee value
2. Summaries of contract/grant activity by grantee Billing summaries by test and unit cost for situations where the contract/grant is disbursed on the basis of work performed
3. Billing summaries by test and unit cost for situation where the contract/grant is disbursed on the basis of work performed

### **Specifications for FR #10: Training, Education and Resource Management**

Overview: It is very important to note that it is not the intent to create a human resources management system within LIMS. In general, if a laboratory is using a human resources management system it is for a larger governmental unit. However, there are a number of critical data elements that pertain only to laboratory testing capabilities: primarily certification and proficiency on a given instrument and method. To capture instrument-specific information in a general human resources system would not be feasible from the standpoint of the particularity of the data. By the same token, the information must be readily available for use with other related LIMS data. Thus, the only logical conclusion is that the data sets required for the support of the LIMS specific training, education, and resource management (data such as instrument preventive maintenance) must be incorporated in the LIMS to effectively support the laboratory's data needs in this regard.

Workflow summary for Training and Education: Create employee (primarily laboratory technicians) training record and populate it with relevant training and education experience, monitor records and testing trends to determine training needs, determine training opportunities and schedule training, and record training in employee record.

Workflow summary for SOP Management: Create records for each SOP and track changes and new versions SOPs have been developed. Provide version control capability with person and time includes approvals.

Workflow summary for Resource (Instrument) Management: Create records for each instrument and instrument method if multiple methods are used on a given instrument, track instrument preventive and emergency maintenance, track next preventive maintenance date, and monitor instrument usage.

Specific requirements for each training workflow area:



1. Create and maintain laboratory technician training records
  - 1.1. Ability to create and maintain employee records pertaining to specialized training, such as date of employment, qualifications, list of certificates, list of assigned instruments/devices, list of specific analytical methods the technician is able to perform, etc.
  - 1.2. Ability to track employee immunization status (if needed)
  - 1.3. Ability to create and maintain code tables for training activities
2. Monitor records for training needs
  - 2.1. Ability to create and maintain business rules associated with each training activity including time intervals between “refresher” sessions
  - 2.2. Ability to flag employee training records when additional training is required and create reminders
  - 2.3. Ability to forecast training needs for specified time period (for example, projections for next 12 months by type of training)
3. Determine training opportunities and schedule training
  - 3.1. Create calendar for training offerings that can be accessed by employees and submitters (for example, instructions on specimen/sample packaging and shipping) for self-enrollment
  - 3.2. Ability to send reminder via email to the enrolled staff or flag in the LIMS at least two weeks prior to the scheduled training date
4. Record training and proficiency information
  - 4.1. Ability to record training received in laboratory supported training as well as external training attended
  - 4.2. Ability for employees to view their training records
5. Track QC/QA issues and institute training for problem correction (both laboratory personnel and submitters)
  - 5.1. Create and schedule training specifically addressed to correct QC or QA problems

#### **Specific requirements for SOP management workflow area**

##### **1. Create records for each SOP**

1. Ability to create and maintain master records for each SOP with version information, such as person and time
2. Ability to create and maintain history of changed SOPs
3. Ability to create and maintain list of printed SOPs and their location

#### **Selected system output requirements**

1. Current SOP list and location including electronic and page SOPs
  2. List of SOPs with version and modification change history
- Specific requirements for each resource (instrument/device) management workflow area

1. Create records for each instrument/device and instrument/device method
  - 1.1. Ability to create and maintain master records for each instrument and associated method and periodic verification of minimum detection limits (MDL)
  - 1.2. Ability to create and maintain master records for each instrument/device information including date of installation, date of validation/verification, standard samples for use
  - 1.3. Ability to create and maintain documentation list of instruments/devices including manufacture name, model, serial number, location, certificates, manual, acts, and printed manual location
  - 1.4. Ability to create list of technician assigned to the instruments/devices
  - 1.5. Ability to analyze test /method volumes and create capacity/day for each instrument/device method
  - 1.6. Ability to track preventive and emergency maintenance activity by instrument/device, including average “down time” for a preventive maintenance and average down time per month associated with emergency maintenance
  - 1.7. Ability to schedule instrument preventative maintenance and associated down time.
  
2. Track instrument/device preventive and emergency maintenance
  - 2.1. Ability to create date(s) of calibrations for each instrument/device
  - 2.2. Ability to create message on approach of term of calibration in one month prior to the termination of term and send to responsible staff by email and SMS
  - 2.3. Ability to create dates of instruments/devices maintenance
  - 2.4. Ability to create list of instruments/devices intermediate measurements
  - 2.5. Ability to record actual down time for preventive and emergency maintenance
  - 2.6. Ability to send email and SMS to responsible staff violations or deviations information when instruments/devices run on automatic mode
  
3. Monitor instrument/device usage (tests by method)
  - 3.1. Ability to report on test volumes and times by instrument/device and method

**Selected QA specifications**

1. Ability to capture specific data elements associated with QA measures associated with this business process (see Business Process #14 for additional information)

**Selected system output requirements**

1. Current training schedule and associated information
2. Schedule of special education (as needed depending on QA problems) and intended audience
3. Reports of available qualified personnel counts by instrument
4. Electronic instrument/device availability schedule and utilize it in scheduling activities
5. Instrument/device maintenance schedules
6. Reports of instruments/devices information mentioned above
7. Email and SMS message to responsible staff mentioned above

## **8.6 Integration with other application**

Proposed system is expected to act as a one single platform of FDL for all the stakeholders entering or viewing information related to concerned subject matters. The proposed system should be capable of integration (API based) with external systems like:

To allow for exchange of data and communication electronically with these systems. SP will be responsible for publishing API's related with the proposed system only and APIs of other external applications will be provided by tenderer. Successful bidder will only consume the said API and publish the API for other systems.

**Bidder is expected to do following integration in phase 2 or Operation and maintenance phase.**

### **Integration with CM Dashboard.**

- CM Dashboard has been designing to monitor the Key Performance Indicator of the various Sector of the state.
- SI shall provide the web service of the Identified Key Performance Indicator of the application.

### **Integration with IFMS.**

- IFMS (Integrated Finance Management System) has been design and developed by Finance Department for Finance Management of the state.
- SI shall provide the Integration with IFMS or any new application implement by Finance Department for the RTI fees reconciliation

### **Integration with IWDMS**

- IWDMS (Integrated Work Flow and Document Management System) developed for the online File/Tappla Processing of GoG and implemented in Secretariat and HoD Level.
- SI shall provide the integration with IWDMS or any new application implement for File/ Tappal processing of GoG.

### **Integration with Common Service Portal (CSP)**

- Common Service Portal has development and implemented to provide the Citizen Centric Service through single portal.
- SI shall provide the integration with CSP.

## **8.7 Training:**

- The SI shall provide the training of application to 500 users.
- Department will provide the infrastructure for training viz. Conference room, Computers, Seating, Furniture, Network Bandwidth, Consumables like pens, white boards, projectors, chalk, duster, paper pins etc. for Training. The reference/training material will be provided by the bidder. The logistic for the

trainer will be arranged by the bidder. However, the logistic for the trainee will be arranged by the FDL.

**Deliverables:**

1. Training Plan – One Electronic Copy
2. Training Material – One Electronic Copy to the Nodal Officer
3. Training Report containing Exist Test Result and Training Feedback – One Electronic Copy to FDL

**Project Management Structure**

The bidder needs to provide detailed Project Management Structure along with the required manpower for successful execution of project. The following are the details of the Project Management Services to be offered of Proposed Developed Application as defined in their respective Scope of Works:

- The objective of the Project Management Service is to provide a systematic approach to managing the project from inception through implementation for 5 years after Final Acceptance Test and finally delivery of the system / services.
- The project management involvement is throughout the entire project life cycle from Datacenter pre-planning, project kick-off, project inception, project design, Infrastructure implementation, deployment, FAT to project hand-over for operations and maintenance.
- Overall responsibility - To manage the Proposed Developed Application through to project delivery, implementation, customer acceptance and project closure.
- To setup and manage Project Management team consisting of all constituents who are involved in the roll out of the Successful implementation
- To enforce work process structure and methodologies to enable the project team to perform their tasks effectively
- Central tracking of all project status from inception to production
- To manage project plan schedules for timely delivery for all activities as mentioned in bid
- To manage Customer's expectations and communications
- To manage quality, issues and change and escalations of implementation
- To identify project variances and steps to be taken to recover to the project plan
- Reporting – To provide timely and accurate updates, reports and escalations to Food and Drug Laboratory and its designated Agency's senior management on the health of project delivery operations.

- To manage different Partners for the delivery of the project
- To highlight technology risks and red alerts, if any.
- To plan for live operation of the proposed systems
- To manage the deployment of the new systems
- To organize project reviews and evaluation
- To gather and manage project documentation
- To obtain sign-offs for project deliverables

### **Exit Management Plan**

- After completion of 4th year of Maintenance, FDL office shall identify and propose its Information Technology operations team to take over the software maintenance activities from the SI
- The SI shall create a detailed plan for Capacity Building required at FDL office to manage the application and a Transition Plan (implemented over a minimum period of 1 year) to affect the handover to FDL office; and implement the same in collaboration with the FDL office before the completion of their engagement.
- The SI shall handover all the documents, source codes to FDL office's IT Team during the 5<sup>th</sup> year of operations. This will include training and transfer of Intellectual Property, Knowledge Transfer related to maintenance as per FDL office's requirement

### **Change Management**

- Introducing any change needs to consider the impact that change will have on all stakeholders – both within and outside the FDL. It is therefore necessary, for the SI, to formulate a change management strategy that encompasses the requirements of the end user and the employees. The SI should ensure that change management starts from the project planning stage and continues throughout the life of the project. It is essential to understand that change management is not a onetime activity. It is a continuous activity propagating to complete life of the project and touching all the stakeholders involved in the project
- The Change Management Plan suggests the key strategies needed to address the aforementioned change implications having highest impact.
- The developer team shall have to prepare a draft change plan which it will present to the project team in FDL for approval. After incorporating changes proposed by the FDL, the developer team shall operationalize the change management plan.

## **8.8 Project execution Stages:**

### **Stage I: Design Phase**

- Documentation of the existing processes of FDL
- Document existing processes Levels of FDL.
- Propose process Levels, based upon benchmarking / opportunities for improvement of processes.
- Identification of Business Process Reengineering requirement to achieve the proposed service levels, including legal changes required in processes.
- Documentation of To-Be Process maps in line with the BPR proposed of processes.
- Design the User Requirements Specification.
- Capacity Building / Training Plan
- Prepare System Requirement Specification (SRS) for application development
- Design the Change Management Plan
- Design and seek approval of the implementation Strategy from FDL prior to the commencement of the implementation plan
- Design & documentation of Hardware, network architecture & other infrastructural requirements, based on applications to be developed and submit Bill of Material to the FDL which will be procured by FDL separately.

### **Stage II: Implementation Phase**

- Software development, integration, testing & deployment
- Project monitoring and progress reporting to the FDL on regular basis.
- Complete entire solution wide roll out will be started within timeline of contract and then completed in a years' timeframe once it is started. The SI will work with FDL to develop project implementation schedule immediately after the award of work order and will complete the schedule within a month's time.
- Development of UAT procedures and test cases
- Provide database software or any other software needs to run the Application.
- Bug fixing and incorporate feedback from Users.
- End User Training
- Rollout/Implementation of Application at least one locations mentioned in the geographical scope.
- Interface with front end delivery centers for application Go-Live
- Application Testing through EQDC and Security audit of the application through CERT-In empaneled agency.

### **Stage III: Post Implementation – Warranty and Support**

- SI will be responsible for providing support, in terms of product support, during contract period from the date of the application software.

#### **8.9 Operation and Maintenance Support**

- The SI has to provide the operation & maintenance for the period of 5 years Resolution of errors/bugs (if any), software updates, patches, changes in the software that may be necessary due to legal/statutory/GR/Any ACT etc. changes.
- Ongoing technical support for application
- Fine Tuning updates/patches reporting
- Fixing logical/run-time errors in the applications
- Development, Testing and Implementation for Bug-Fixes
- Generate reports on changes made in applications
- Generate reports on change given to support team
- System administration and database management support
- Deployment of new application on production servers
- Synchronize the application release in all application servers of FDL.
- Maintaining checklist for the status of deployment on all servers
- Monitoring & Reporting Server/ System performance
- Backup/Restore data

#### **Development and O & M Team**

##### **8.9.1 Bidder shall propose the development Team for project as follow**

Bidder shall propose development team with efficient resource to develop application in prescribed timeline. The developer team resources will be based Onsite at a location/premises to be provided by Government of Gujarat.

##### **8.9.2 Bidder shall propose the Operation and Maintenance team for project as follow**

After the rollout, the service provider shall keep three types of resource team at FDL during the entire duration of O & M.

###### **a) Developer Team**

For Continues development process of web application a team of 2 developers with minimum 5 years of experience in development of similar application shall be provided. (Team Deployment 100% Onsite)

###### **b) O & M Team**

To support the technical support for hardware/software, web application including applying patching, antivirus updation, DB Management, O & M team of following resources shall be provided.

- I. Project manager with (IT Graduate + MBA/PG with minimum 5 years of experience and domain knowledge) separate from the developer team of O & M mentioned above. (Team Deployment 100% Onsite)
- II. Central Site O & M Team: System Administrator, System/Business Analyst, DBA, Security Expert, Network Administrator, Portal Expert, and Mobility Expert etc. with BE/MCA/PG in IT having minimum 3 to 5 years of experience in their respective field. (Need Basis)

The manpower for O & M support of the application should be at least graduate and having 1 year of experience in Operation & Maintenance support of IT software/application.

The helpdesk service should be available from 9:00 to 7:00 hrs and as and when any critical issue arises, on call/onsite support need to be available any time.

In case of absent of the manpower, bidder has to provide the alternate arrangement to carry out the activities. In case the resource has resigned then the bidder has to inform within one week of such resignation.

SP shall promptly deploy a replacement to ensure that the role of any member of the Key Personnel is not vacant for any longer than 7 days, subject to reasonable extensions requested by SP Vendor.

Before assigning any replacement member of the Key Personnel to the provision of the Services, SP shall provide:

a resume, curriculum vitae and any other information about the candidate that is reasonably requested; and an opportunity to interview the candidate.

The bidder has to ensure at least 4 weeks of overlap period in such replacements

Operation and Maintenance Period bidders are expected to carry out change that is required due to change in functionalities, Act, Rule, GR etc. during the 5 years of Operation and Maintenance period with the help of above mentioned team. No additional payment will be made during O & M period. During the course of O & M, bidder may suitably- deploy more resources, if required to perform any changes in the developed application.

c) The scope of services to be offered by bidder is detailed below:

- Provide warranty/on-site maintenance product, software that shall be supplied and installed under this procurement throughout the period of



contract as per SLA and also provide warranty execution/onsite maintenance of the Database S/W.

- Undertake Performance Tuning and ensuring optimum performance of the equipment supplied. The support coverage shall be as per the service window mentioned in the Section – “Service Level”.
- Provide manpower for operations, maintenance and onsite warranty support of all the existing and supplied items.
- Bidder is required to propose the required compute power, storage and other requirement to host the FDL application at Central site. The necessary compute infrastructure will be provided by Govt. of Gujarat.
- FDL application will be hosted on this cloud infrastructure. For storage, EMC VMA 200K storage will be provided.
- **As a part of technical bid, the detail BoM required is to be proposed as below:**

▪ Bill of Material for Hardware

Sr. No.	*Description	vCPU	RAM	HDD Space	Quantity	Remarks, if any

\*Description: required DB servers, app servers, reporting servers or any other server (for production, testing development etc), equipment required for running the application at DC

1 physical core = 2 vCPU

▪ Bill of Material for Software

Sr. No.	*Product Description	Unit of Measurement	Licenses quantity for DC	Remarks, if any

\*Description: Required all the readymade software including OS and Database, App, Web, BI etc. for DC

In State Data Center the required compute infrastructure and storage will be provided. However, bidder has required to quote, supply, install and maintain the required OS, Database and other s/w licenses provided by bidder. Considering the 5 years of growth if more compute infrastructure and storage will be required than it will be provided by Department. However, the incremental licenses of the OS and Database is required to be supplied and maintained with required ATS/AMC by

bidder during 5 years of O & M period as part of this bid. The bidder has to envisage incremental licenses and AMC/ATS cost and the quote for the same in financial bid.

**Technical Details:**

- Application type: Three tier web based application
- Technology Platform: Any
- Back end Technology: Any
- Server OS Support: Non Unix Environment
- The application developer/software provider should ensure that the proposed application architecture & offered solution including hardware, software or any other tool should be latest and should not be end of support/end of sales during the 5 years of O & M period.
- The proposed solution should be on open standard and compatible with other technology. So that, there should not be any proprietary/OEM lock in situation during the 5 years of O & M period.
- After completion of 5 years and at the time of handover takeover, SI has to provide the application with latest technology version, update and upgrades.
- Every 6 months, Bidder has to submit the documentation including code structure and architecture.

## 9 SECTION IX: Forms of Qualification and Technical Bid

### 9.1 Form I: Bid Proposals Form

Date:

Tender No.: GIL/ \_\_\_\_\_

To

Dear Sir,

Having examined the Bidding Documents including Addenda Nos. \_\_\_\_\_ (insert numbers, if any), the receipt of which is hereby duly acknowledged, we, the undersigned, offer to render the services as mentioned in the scope of work to “To Design, Development, and implementation of the web based LIMS for Food and Drug Laboratory, Vadodara” in conformity with the said bidding documents for the same as per the technical and financial bid and such other sums as may be ascertained in accordance with the Financial Bid attached herewith (Annexure B) and made part of this bid. We have not placed any condition for the bid on our part and agree to bind ourselves to the terms and conditions of this tender unconditionally. Any conditions placed by us elsewhere in the present bid are hereby withdrawn unconditionally.

We undertake, if our bid is accepted, to render the services in accordance with the delivery schedule which will be specified in the contract document that we will sign if the work order given to us.

If our bid is accepted, we will obtain the guarantee of a bank for the sum indicated as per tender document for the due performance of the Contract, in the form prescribed by FDL.

We agree to abide by this bid for a period of 180 (One hundred and eighty only) days after the date fixed for bid opening of the Instruction to Bidders and it shall remain binding upon us and may be accepted at any time before the expiration of that period.

Until a formal contract is prepared and executed, this bid, together with your written acceptance thereof and your notification of award shall constitute a binding Contract between us.

Name:

Address:

We understand that you are not bound to accept the lowest or any bid you may receive.

Dated this day of 2019

Signature (in the capacity of)

Duly authorized to sign Bid for and on behalf of

## 9.2 Form II: BIDDER'S CHECK LIST

Sr. No	Criterion	Compliance Yes/No	Page No./Name of Attachment
1	EMD & Bid Processing Fee	Yes/No	
2	Certifications	Yes/No	
3	Past Experience	Yes/No	
4	Annual Turnover and CA Certificate	Yes/No	

**9.3 Form III: Particular of Bidders Organization.**

Sr. No	Particulars	Details to be furnished	
1.	Details of responding company		
a)	Name		
b)	Address		
c)	Telephone		Fax
d)	Website		
2.	Details of Contact Person		
a)	Name		
b)	Designation		
c)	Address		
d)	Telephone no.		
e)	Mobile no.		
f)	Fax no.		
g)	E-mail		
3.	Details of Authorized Signatory (please attach proof)		
a)	Name		
b)	Designation		
c)	Address		
d)	Telephone no.		
e)	Mobile no.		
f)	Fax no.		
g)	E-mail		
4.	Information about responding company (please attach proof)		
a)	Status of company (Public Ltd. / Pvt. Ltd etc)		
b)	No. of years of operation in India		
c)	Details of Registration	Date	
d)	Details of Quality Certifications for Documentation & processing		
e)	Locations and addresses of offices (In Gujarat & India)		

**9.4 Form IV: Bid Processing Fees & EMD Details**

Sr No	Item	Amount (Rs.)	Name of Bank & Branch	Demand Draft /BG No.
1	Bid Processing Fees			
2	EMD			

**9.5 Form V: Format for Financial Capability**

Financial Year	Turnover (Rs. In Cr.)

**9.6 Form VI: Detail of similar type of Project (Successfully Completed or Ongoing)**

Name of department (with address contact persons and numbers)	Brief Description of projects	Responsibility or role of the Bidder in the Project	Order value (Rs)	Completion Date (approx.)

(Please attach relevant client certificates/Work Order/PO/Contract Document highlighting the No. of Documents)

**9.7 Form VII: Work Plan**

In this chapter you should propose the main activities of the assignment, their content and duration, phasing and interrelations, milestones (including interim approvals by the Client), and delivery dates of the reports. The proposed work plan should be consistent with the technical approach and methodology, showing understanding of the scope of services and ability to translate them into a feasible working plan. A list of the final documents, including reports, drawings, and tables to be delivered as final output, should be included here. The work plan should be consistent with the Work Schedule.

Work Plan

S No	Activity	Months							
		1	2	3	4				n
1									
2									
3									
4									

n									
---	--	--	--	--	--	--	--	--	--

- 1 Duration of activities shall be indicated in the form of a bar chart.
- 2 The work schedule should reflect how and by when the bidder is expected to complete the assignment for each of the component and how this work plan maps to the resource schedule given earlier.
- 3 Indicate all main activities of the assignment, including delivery of reports (e.g.: inception, interim, and final reports), and other benchmarks such as Purchaser approvals. For phased assignments indicate activities, delivery of reports, and benchmarks separately for each phase.
- 4 Table can be customized as per need.

**9.8 Form IX: Description of the Approach, Methodology and Work Plan for Performing the Assignment**

Technical approach, methodology and work plan are key components of the Technical Proposal. Bidders are suggested to present their Technical Proposal (inclusive of charts and diagrams) including Technical Approach and Methodology, Technical Approach and Methodology -In this chapter you should explain your understanding of the objectives of the assignment, approach to the services, methodology for carrying out the activities and obtaining the expected output, and the degree of detail of such output. You should highlight the problems being addressed and their importance, and explain the technical approach you would adopt to address them. You should also explain the methodologies you propose to adopt and highlight the compatibility of those methodologies with the proposed approach.

**9.9 Form X: Self-Declaration**

The  
 -----,  
 -----

Sir/Madam,  
 Having examined the Bidding Documents including Bid No.: ----- the receipt of which is hereby duly acknowledged, we, the undersigned, offer to provide services for -----

We undertake, if our bid is accepted, to provide \_\_\_\_\_, in accordance with the terms and conditions in the tender document.

If our bid is accepted we will obtain the guarantee of a bank for a sum equivalent to 10% of the Contract value, in the form prescribed by the purchaser.

We agree to abide by this bid for a period of 180 days after the date fixed for opening of Price Bid section under the Instruction to Bidders and shall remain binding upon us and may be accepted at any time before the expiry of that period.

Until a formal contract is prepared and executed, this bid, together with your written acceptance thereof and your notification of award shall constitute a binding Contract between us.

We understand that in competing for (and if the award is made to us, in executing the above contract), we will strictly observe the laws against fraud and corruption in force in Gujarat namely Prevention of Corruption Act 1988.

We understand that you are not bound to accept the lowest or any bid you may receive.

We have not been under a declaration of ineligibility for corrupt and fraudulent practices, and / or black-listed or debarred by any of the Govt. Department or its PSU in the past 5 years in Gujarat as on bid submission date. We have not imposed any condition in conflict with the tender condition if it is found it should be treated as withdrawn.

We have not been convicted for any criminal cases(s) by any of the Govt. Department or its PSU in Gujarat regarding any supply and contracts with our firm/company.

We have not breached/violated any contractual conditions so far to any of the Govt. Department or its PSU.

In case any of the above statements made by us are found to be false or incorrect, you have right to reject our bid at any stage including forfeiture of our EMD and / or PBG and / or cancel the award of contract

Dated this \_\_\_\_\_ day of \_\_\_\_\_ 20\_\_

Signature: \_\_\_\_\_

(in the Capacity of): \_\_\_\_\_

Duly authorized to sign bid for and on behalf of



## 10 Financial Bid Format

### Phase 1 – Core LIMS implementation

#	Particular	Total Cost (Rs.)
<b>Phase 1 – Core LIMS implementation</b>		
1	Design, Develop, Test , Implement and Train for web based LIMS application as per the Scope of Work mention in the RFP – <b>Part 1</b>	
2	Cost of the Software products like OS, Database or any other third-party software required to run the LIMS application for 5 years – <b>Part 2</b>	
3	ATS/AMC of Software products like OS, Database or any other third party software required to run the LIMS application for 5 years – <b>Part 3</b>	
4	Cost of LIMS Operation and Maintenance support for 5 years – <b>Part 4</b>	
<b>Phase 2 – ERP Module implementation</b>		
5	Design, Develop, Test , Implement and Train for web based ERP Module application as per the Scope of Work mention in the RFP – <b>Part 5</b>	
6	Cost of the Software products like OS, Database or any other third-party software required to run the ERP Module application for 5 years – <b>Part 6</b>	
7	ATS/AMC of Software products like OS, Database or any other third party software required to run the ERP Module application for 5 years – <b>Part 7</b>	
8	Cost of ERP Module Operation and Maintenance support for 5 years – <b>Part 8</b>	
<b>Grand Total (Item no. 1+2+3+4+5+6+7+8) (Rs.)</b>		

Note:

- Taxes are extra as applicable
- Grand total will be considered for final evaluation.
- The cost of the above parts should be matched with the breakup of each component mentioned in Part.

### Part 1: Design, Develop, Test , Implement and Train for web based LIMS application as per the Scope of Work mention in the RFP

Sr No	Item Description Original	Total Man-month Efforts	Rate per man-month	Total amount (Rs.)
		A	B	C= A* B

1	Conceptualization, As-Is Scenario, BPR and To-be			
2	Finalizing URS, SRS for application			
3	Development/ Customization & Coding			
4	Design, Development and Coding			
Total Amount (Rs.)				

**Part 2: Cost of the Software products like OS, Database or any other third-party software required to run the LIMS application for 5 years**

Sr No.	Item (License Software)	Qty.	Unit Price (Rs.)	Total Amount(Rs.)
A	B	C	D	E=C*D
1				
2				
3				
4				
Total Amount (Rs.)				

**Part 3: ATS/AMC of Software products like OS, Database or any other third party software required to run the LIMS application for 5 years**

Sr No.	Item (License Software)	Qty.	Y1 (Rs.)	Y2 (Rs.)	Y3 (Rs.)	Y4 (Rs.)	Y5 (Rs.)	Total (Rs.)
A	B	C	D	E	F	G	H	I=(D+E+F+G+H)
1								
2								
3								
4								
5								
Total Amount (Rs.)								

**Part 4: Cost of LIMS Operation and Maintenance support for 5 years including continuous development team and training and central site O&M team for Technical support for Software Upgrades, Updates, patches, security updates, bug fixes etc.**

S/n	Particular	No. of Resource	Year 1	Year 2	Year 3	Year 4	Year 5	Total=(E+G+I+K+M)

			Per month Rate (Rs.)	Y1=(C*D*12)	Per month Rate (Rs.)	Y2=(C*F*12)	Per month Rate (Rs.)	Y3=(C*H*12)	Per month Rate (Rs.)	Y4=(C*J*12)	Per month Rate (Rs.)	Y5=(C*L*12)	
A	B	C	D	E	F	G	H	I	J	K	L	M	N
1.													
2.													
3.													
4.													
5.													
6.													
Total Amount (Rs.)													

**Part 5: Design, Develop, Test , Implement and Train for web based ERP Module application as per the Scope of Work mention in the RFP**

Sr No	Item Description Original	Total Man-month Efforts	Rate per man-month	Total amount (Rs.)
		A	B	C= A * B
1	Conceptualization, As-Is Scenario, BPR and To-be			
2	Finalizing URS, SRS for application			
3	Development/ Customization & Coding			
4	Design, Development and Coding			
Total Amount (Rs.)				

**Part 6: Cost of the Software products like OS, Database or any other third-party software required to run the ERP Module application for 5 years**

Sr No.	Item (License Software)	Qty.	Unit Price (Rs.)	Total Amount(Rs.)
A	B	C	D	E=C*D
1				
2				
3				
4				
Total Amount (Rs.)				

**Part 7: ATS/AMC of Software products like OS, Database or any other third party software required to run the ERP Module application for 5 years**

Sr No.	Item (License Software)	Qty.	Y1 (Rs.)	Y2 (Rs.)	Y3 (Rs.)	Y4 (Rs.)	Y5 (Rs.)	Total (Rs.)
A	B	C	D	E	F	G	H	I=(D+E+F+G+H)
1								
2								
3								
4								
5								
Total Amount (Rs.)								

**Part 8: Cost of ERP Module Operation and Maintenance support for 5 years including continuous development team and training and central site O&M team for Technical support for Software Upgrades, Updates, patches, security updates, bug fixes etc.**

S/n	Particular	No. of Resource	Year 1		Year 2		Year 3		Year 4		Year 5		Total=(E+G+I+K+M)
			Per month Rate (Rs.)	Y1=(C*D*12)	Per month Rate (Rs.)	Y2=(C*F*12)	Per month Rate (Rs.)	Y3=(C*H*12)	Per month Rate (Rs.)	Y4=(C*J*12)	Per month Rate (Rs.)	Y5=(C*L*12)	
A	B	C	D	E	F	G	H	I	J	K	L	M	N
1.													
2.													
3.													
4.													
5.													
6.													
Total													

**11Annexure A: Performance Bank Guarantee**

(To be stamped in accordance with Stamp Act)

Ref:

Bank Guarantee No.

Date:

To

Name & Address of the Purchaser/Indenter

\_\_\_\_\_  
\_\_\_\_\_

Dear Sir,

In consideration of Name & Address of the Purchaser/Indenter, Government of Gujarat, Gandhinagar (hereinafter referred to as the OWNER/PURCHASER which expression shall unless repugnant to the context or meaning thereof include successors, administrators and assigns) having awarded to M/s.

.....  
..... having Principal Office at

..... (hereinafter referred to as the "SELLER" which expression shall unless repugnant to the context or meaning thereof include their respective successors, administrators, executors and assigns) the supply of \_\_\_\_\_ by issue of Purchase Order No..... Dated ..... issued by Gujarat Informatics Ltd. ,Gandhinagar for and on behalf of the OWNER/PURCHASER and the same having been accepted by the SELLER resulting into CONTRACT for supplies of materials/equipment's as mentioned in the said purchase order and the SELLER having agreed to provide a Contract Performance and Warranty Guarantee for faithful performance of the aforementioned contract and warranty quality to the OWNER/PURCHASER, \_\_\_\_\_having Head Office at (hereinafter referred to as the 'Bank' which expressly shall, unless repugnant to the context or meaning thereof include successors, administrators, executors and assigns) do hereby guarantee to undertake to pay the sum of Rs. \_\_\_\_\_ (Rupees \_\_\_\_\_) to the OWNER/PURCHASER on demand at any time up to \_\_\_\_\_ without a reference to the SELLER. Any such demand made by the OWNER/PURCHASER on the Bank shall be conclusive and binding notwithstanding any difference between Tribunals, Arbitrator or any other authority.

The Bank undertakes not to revoke this guarantee during its currency without previous consent of the OWNER/PURCHASER and further agrees that the guarantee herein contained shall continue to be enforceable till the OWNER/PURCHASER discharges this guarantee. OWNER/PURCHASER shall have the fullest liberty without affecting in any way the liability of the Bank under this guarantee from time to time to extend the time for performance by the SELLER of the aforementioned CONTRACT. The OWNER/PURCHASER shall have the fullest liberty, without affecting this guarantee, to postpone

from time to time the exercise of any powers vested in them or of any right which they might have against the SELLER, and to exercise the same at any time in any manner, and either to enforce to forebear to enforce any covenants contained or implied, in the aforementioned CONTRACT between the OWNER/PURCHASER and the SELLER or any other course of or remedy or security available to the OWNER/PURCHASER.

The Bank shall not be released of its obligations under these presents by any exercise by the OWNER/PURCHASER of its liability with reference to the matters aforesaid or any of them or by reason or any other acts of omission or commission on the part of the OWNER/PURCHASER or any other indulgence shown by the OWNER/PURCHASER or by any other matter or things.

The Bank also agree that the OWNER/PURCHASER at its option shall be entitled to enforce this Guarantee against the Bank as a Principal Debtor, in the first instance without proceeding against the SELLER and not withstanding any security or other guarantee that the OWNER/PURCHASER may have in relation to the SELLER's liabilities.

Notwithstanding anything contained herein above our liability under this Guarantee is restricted to Rs. \_\_\_\_\_ (Rupees \_\_\_\_\_) and it shall remain in force up to and including \_\_\_\_\_ and shall be extended from time to time for such period as may be desired by the SELLER on whose behalf this guarantee has been given.

Dated at \_\_\_\_\_ on this \_\_\_\_\_ day of \_\_\_\_\_ 201\_\_

\_\_\_\_\_  
Signed and delivered by

\_\_\_\_\_  
For & on Behalf of

Name of the Bank & Branch &  
Its official Address

## 12Annexure B: Format of Earnest Money Deposit in the form of Bank Guarantee

Ref:

Bank Guarantee No.

Date:

To,  
DGM (Application Development)  
Gujarat Informatics Limited  
8th Floor, Block -1, Udyog Bhavan,  
Sector - 11, Gandhinagar - 382017  
Gujarat, India

Whereas ----- (here in after called "the Bidder") has submitted its bid dated ----- in response to the Tender no: SWT10102019185 for "To Design, Development, and Implementation of the web based Online RTI Application Processing for Food and Drug Laboratory" KNOW ALL MEN by these presents that WE -----  
----- having our registered office at -----  
----- (hereinafter called "the Bank") are bound unto the \_\_\_\_\_, Gujarat Informatics Limited in the sum of ----- for which payment well and truly to be made to Gujarat Informatics Limited, the Bank binds itself, its successors and assigns by these presents. Sealed with the Common Seal of the said Bank this -----day of -----2019.

THE CONDITIONS of this obligation are:

- The E.M.D. may be forfeited:
  - a. if a Bidder withdraws its bid during the period of bid validity
  - b. Does not accept the correction of errors made in the tender document;
  - c. In case of a successful Bidder, if the Bidder fails:
    - (i) To sign the Contract as mentioned above within the time limit stipulated by purchaser or
    - (ii) To furnish performance bank guarantee as mentioned above or
    - (iii) If the bidder is found to be involved in fraudulent practices.
    - (iv) If the bidder fails to submit the copy of purchase order & acceptance thereof.

We undertake to pay to the GIL/Purchaser up to the above amount upon receipt of its first written demand, without GIL/ Purchaser having to substantiate its demand, provided that in its demand GIL/ Purchaser will specify that the amount claimed by it is due to it owing to the occurrence of any of the abovementioned conditions, specifying the occurred condition or conditions.

This guarantee will remain valid up to 9 months from the last date of bid submission. The Bank undertakes not to revoke this guarantee during its currency without previous consent of the OWNER/PURCHASER and further agrees that the guarantee herein contained shall continue to be enforceable till the OWNER/PURCHASER discharges this guarantee

The Bank shall not be released of its obligations under these presents by any exercise by the OWNER/PURCHAER of its liability with reference to the matters aforesaid or any of them or by reason or any other acts of omission or commission on the part of the OWNER/PURCHASER or any other indulgence shown by the OWNER/PURCHASER or by any other matter or things.

The Bank also agree that the OWNER/PUCHASER at its option shall be entitled to enforce this Guarantee against the Bank as a Principal Debtor, in the first instance without proceeding against the SELLER and not withstanding any security or other guarantee that the OWNER/PURCHASER may have in relation to the SELLER's liabilities.

Dated at \_\_\_\_\_ on this \_\_\_\_\_ day of \_\_\_\_\_ 201\_\_.

\_\_\_\_\_

Signed and delivered by

\_\_\_\_\_

For & on Behalf of

Name of the Bank & Branch &  
Its official Address

**Approved Bank: Any Nationalized Bank including the public sector bank or Private Sector Banks or Commercial Banks or Co-Operative Banks and Rural Banks (operating in India having branch at Ahmedabad/ Gandhinagar) as per the G.R. no. EMD/10/2018/18/DMO dated 16.04.2018 issued by Finance Department or further instruction issued by Finance department time to time.**



**13 Annexure C: Format of Affidavit**  
**(TO BE SUBMITTED PHYSICALLY)**

(To be submitted IN ORIGINAL on Non-Judicial Stamp Paper of Rs 100/- duly attested by First Class Magistrate/ Notary public)

I/We, \_\_\_\_\_, age \_\_\_\_\_ years residing at  
\_\_\_\_\_ in \_\_\_\_\_ capacity of  
\_\_\_\_\_ M/s.  
\_\_\_\_\_ hereby solemnly affirm that

- 1) All General Instructions, General Terms and Conditions, as well as Special Terms & Conditions laid down on all the pages of the Tender Form, have been read carefully and understood properly by me which are completely acceptable to me and I agree to abide by the same.
- 2) I / We have submitted following Certificates / Documents for T.E. as required as per General Terms & Conditions as well as Special Terms & Conditions of the tender

Sr. No.	Name of the Document
1	
2	

- 3) All the Certificates / Permissions / Documents / Permits / Affidavits are valid and current as on date and have not been withdrawn / cancelled by the issuing authority.
- 4) It is clearly and distinctly understood by me that the tender is liable to be rejected if on scrutiny at any time, any of the required Certificates / Permissions / Documents / Permits / Affidavits is / are found to be invalid / wrong / incorrect / misleading / fabricated / expired or having any defect.
- 5) I / We further undertake to produce on demand the original Certificate / Permission / Documents / Permits for verification at any stage during the processing of the tender as well as at any time asked to produce.
- 6) I / We also understand that failure to produce the documents in "Prescribed Proforma" (wherever applicable) as well as failure to give requisite information in the prescribed Proforma may result in to rejection of the tender.
- 7) My / Our firm has not been banned / debarred / black listed at least for three years (excluding the current financial year) by any Government Department / State Government / Government of India / Board / Corporation / Government Financial Institution in context to purchase procedure through tender.
- 8) I / We confirm that I / We have meticulously filled in, checked and verified the enclosed documents / certificates / permissions / permits / affidavits / information etc. from every aspect and the same are enclosed in order (i.e. in chronology) in which they are supposed to be enclosed. Page numbers are given on each submitted document. Important information in each document is "highlighted" with the help of "marker pen" as required.

- 9) The above certificates / documents are enclosed separately and not on the Proforma printed from tender document.
- 10) I / We say and submit that the Permanent Account Number (PAN) given by the Income Tax Department is \_\_\_\_\_, which is issued on the name of \_\_\_\_\_ [Kindly mention here either name of the Proprietor (in case of Proprietor Firm) or name of the tendering firm;1, whichever is applicable].
- 11) I / We understand that giving wrong information on oath amounts to forgery and perjury, and I/We am/are aware of the consequences thereof, In case any information provided by us are found to be false or incorrect, you have right to reject our bid at any stage including forfeiture of our EMD/PBG/cancel the award of contract. In this event, this office reserves the right to take legal action on me/us.
- 12) I / We have physically signed & stamped all the above documents along with copy of tender documents (page no. ---- to -- ).
- 13) I / We hereby confirm that all our quoted items meet or exceed the requirement and are absolutely compliment with specification mentioned in the bid document.
- 14) My / Our Company has not filed any Writ Petition, Court matter and there is no court matter filed by State Government and its Board Corporation, is pending against our company.
- 15) I / We hereby commit that we have paid all outstanding amounts of dues / taxes / cess / charges / fees with interest and penalty.
- 16) In case of breach of any tender terms and conditions or deviation from bid specification other than already specified as mentioned above, the decision of Tender Committee for disqualification will be accepted by us.

Whatever stated above is true and correct to the best of my knowledge and belief.

**Date:** \_\_\_\_\_ **Stamp & Sign of the Tenderer**

**Place:** \_\_\_\_\_ **(Signature and seal of the Notary)**