



thsti

ट्रांसलेशनल स्वास्थ्य विज्ञान
एवं प्रौद्योगिकी संस्थान

TRANSLATIONAL HEALTH SCIENCE
AND TECHNOLOGY INSTITUTE

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Notice Inviting Tender (NIT)

For

**Selection of Agency for designing, developing, configuring, implementing,
integrating and commissioning of Laboratory Information Management
System software**

at THSTI, NCR- Biotech Science Cluster, Faridabad

(No.: THSTI/NIT/LIMS/2020-21)

Date: 05/10/2020



e-TENDER NOTICE

BID DOCUMENT

[Two bid system]

Notice Inviting Tender

Ref. No. THSTI/NIT/LIMS/2020-21

Date: 05th Oct 2020

On behalf of the Executive Director, THSTI open tender is invited from eligible and interested firms for “Designing, developing, configuring, implementing, integrating and commissioning of Laboratory Information Management System (LIMS) software at THSTI, NCR- Biotech Science Cluster, Faridabad”.

| Title of the Service(s) | Tender Fee | Earnest Money Deposit (EMD) |
|---|------------|-----------------------------|
| 'Selection of Agency for designing, developing, configuring, implementing, integrating, commissioning of Laboratory Information Management System software at THSTI, NCR- Biotech Science Cluster, Faridabad' | Rs. 500/- | Rs. 1,80,000/- |

Tender Fee of INR 500.00 (Non-refundable) and EMD as mentioned above is payable by using online payment portal (<https://thsti.res.in/notification-tender.php>). The approved modes of payments are Net Banking, Debit Card, Credit Card and UPI.

KINDLY NOTE THAT ONLY ONLINE BID WILL BE CONSIDERED AGAINST THIS TENDER. Further, requests for postponement will not be entertained. Bids send by post/Fax/email bids shall be rejected straightway.

To solicit prospective bidders' feedback, on specifications/terms of the Tender, a pre-bid meeting with all the prospective bidders is scheduled to be held on 19/10/2020 at 4:00 PM. The venue of the meeting will be THSTI, Faridabad. Interested bidders are invited to attend the same with a written statement of their queries/observations and suggestions. The interested bidders can also join the meeting online, a link for which will be provided only to those bidders who will submit their request/queries via email to support@thsti.res.in copy to tushar.sharma@thsti.res.in latest by 11:00 AM on (19.10.2020) .

All future corrigendum/amendments etc., if any, will be notified only on the THSTI website or CPPP website. No separate advertisement will be released for the same. Prospective bidders are therefore advised to regularly visit these websites for any such updates.

Executive Director, THSTI reserves the right to accept/ reject any or all tenders in part or in full without assigning any reasons thereof.

Technical Manager (IT),

THSTI

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GLOSSARY

| S.No. | Term | Meaning/Refers to |
|-------|-----------------|---|
| 1 | ISO | International Organization for Standardization |
| 2 | CFR | Code of Federal Regulations |
| 3 | NABL | National Accreditation Board for Testing and Calibration Laboratories |
| 4 | SOP | Standard Operating Procedure |
| 5 | PCR | Polymerase chain reaction machine |
| 6 | FACS | Fluorescence-Activated Cell Sorting Machine |
| 7 | ELISA | Enzyme-Linked Immunosorbent Assay |
| 8 | CPPP | Central Public Procurement Portal of Government of India |
| 9 | INSTITUTE/THSTI | Translational Health Science and Technology Institute, Faridabad |

Part A

Terms and conditions of the Tender

DATA SHEET / TIME LINES

| | |
|--|--|
| Document No | THSTI/NIT/LIMS/2020-21 |
| Name of the Project | 'Selection of Agency for designing, developing, configuring, implementing, integrating, commissioning of Laboratory Information Management System software at THSTI, NCR-Biotech Science Cluster, Faridabad' |
| Brief Scope of Project | Implementation of the suitable LIMS software as per the details. |
| Estimated Cost of the Project | Rs. 90 Lakhs |
| Period of Completion | Within 8 Months from the date of acceptance of the Work Order |
| Non-refundable tender fee | Rs. 500/- |
| Earnest Money Deposit | Rs. 1.8 Lakh |
| Date of publishing of e-Tender | (05.10.2020) |
| Last Date of submission of queries in respect of Pre-bid meeting (Refer details at Tender clause no. 3.2) | 19.10.2020 till 11:00AM |
| Pre-Bid meeting date and time | (19.10.2020 from 04:00 PM onwards) |
| Date for uploading corrigendum in respect to the revision in specifications/ terms of e-TENDER as per pre-bid committee meeting (if any) | (22.10.2020) |
| Last date & time for submission of online bids including tender fee, EMD, Proposal and other document as per NIT. | 4:00 PM, 05.11.2020 |
| Date & Time for Opening of bids | 4:00 PM, 06.11.2020 |

Instructions to Bidders

1. The bidder shall carefully examine and understand the specifications/conditions of the tender document and if required seek clarifications in writing during the pre-bid meeting to ensure that they have understood all specifications/conditions of the tender document. If no such clarifications are sought in writing, it will be taken that the bidder has read, understood and accepted all the terms, conditions and specifications in the tender document.
2. The bidder is required to upload a copy of this tender document, with all pages signed by the authorized person, to confirm that bidder has read and understood the conditions of this tender document and that the proposal is submitted in full understanding and agreement of the requirements of THSTI.
3. All costs associated with such site visit and in preparation and submission of the Bid will have to be bear by the bidder. THSTI will in no case be responsible for such costs, regardless of the conduct or outcome of the bidding process.
4. THSTI reserves its rights to amend any of the terms and conditions of this tender document. Such amendment shall be published on THSTI and CPPP website only and will not be published in newspapers. The bidders are advised to regularly visit the website for any such update.
5. The complete bid shall be without alteration or erasures, except those to accord with instructions issued by the THSTI or as necessary to correct errors made by the bidder, in which case such corrections shall be initialed by the person or persons signing the bid.
6. The bidder shall submit only one option, which is best suitable to meet THSTI requirements.
7. The bids submitted with more options shall be liable to be rejected.
8. The bid prepared by the bidder, as well as all correspondence and documents relating to the bid exchanged by the bidder and THSTI, shall be in English only.
9. The bidder shall base his solution on the basis of continuous availability of support and warranty for at least 2 years, after the specified warranty period.
10. Wherever a specific form is prescribed in the bid document, the bidder shall use the form to provide relevant information. If the form does not provide space for any required information, space at the end of the form or additional sheets shall be used to convey the said information. For all other cases, the bidder shall design a form to hold the required information.
11. The bidder shall explicitly indicate the non-compliance or deviation of the solution offered in the proposal to all the terms, clauses, conditions and specifications stipulated in this tender document. If non-compliance or deviation for any term, clause, condition or specification is not explicitly indicated, it will be construed as compliance and if successful in the bid, the bidder is obligated to comply with all the requirements (excluding those non compliances explicitly accepted by THSTI in writing) in toto. Incomplete tenders are liable to be rejected.
12. Successful bidder shall perform all the obligations specified in accordance with the terms and conditions laid down in this tender document. All details provided by the bidder should be specific to the requirements specified in the tender document. Detailed clarification may be provided by bidder, if so

desired by THSTI. The bidder shall specify the responsibilities of THSTI, if any, separately for the successful implementation of the project.

13. The bidder may furnish any additional information, which he thinks is necessary to establish his capabilities to successfully complete the envisaged work. He is however, advised not to furnish superfluous information. No information shall be entertained after submission of tender documents unless it is called for by the THSTI.
14. Any information furnished by the bidder found to be incorrect either immediately or at a later date, would render him/ bidding firm liable to be debarred from tendering/taking up of work in THSTI.
15. Any variation in the terms and conditions of the general/special conditions for payment, tender fees, security deposit, etc. is not acceptable to THSTI and such tenders will be rejected straight away.
16. Acceptance of tender shall rest with the THSTI which shall not be bound to accept the lowest tender and reserves to itself the right to reject any or all tenders received without assigning any reasons therefore.
17. No subletting or subcontracting of the work will be permitted without the express consent of THSTI.
18. Consortiums are not allowed to participate in this tender.
19. All dispute arising under this contract will be subject to the jurisdiction of Haryana High Court.

Technical Manager (IT)

Notice Inviting Tender (NIT) for Selection of Agency for designing, developing, configuring, implementing, integrating and commissioning of Laboratory Information Management System (LIMS) software at THSTI, NCR- Biotech Science Cluster, Faridabad

1. Introduction:

Translational Health Science and Technology Institute (THSTI) is autonomous research Institutes under the Dept. of Biotechnology, Ministry of Science and Technology, Government of India. THSTI form a pivotal node in a broader cluster of institutes collectively referred to as the NCR Biotech Science Cluster (NCR-BSC) and targeted at specializing in translational research and related endeavors. The cluster is an ambitious initiative that aims to create a unique institutional ecosystem and further synergize resources and infrastructure, coordinated development and maximize societal benefits.

A Laboratory Information Management System (LIMS) is software that allows to effectively manage samples and associated data. By using a LIMS, a lab can automate workflows, integrate instruments, and manage samples and associated information. Additionally, you can produce reliable results more quickly and can track data from sequencing runs over time and across experiments to improve efficiency.

Following objectives are targeted to be achieved with LIMS implementation:

- A. Sample collection, processing and storage
- B. Enabling workflow automation
- C. Centralize access and storage of data
- D. Support regulatory compliance efforts
- E. Track reagents, lots and inventory management
- F. Monitoring equipment performance and maintenance
- G. Integrate instruments and data capture processes
- H. Barcoding for samples
- I. Document control on issuance & validity
- J. Audit Trails
- K. Compliance with ISO 17025:2017 and CFR 21.11

The background, objectives and Scope of Work (SoW) to be accomplished by the bidder are provided in the subsequent sections of this document. The bidders may take note of the following:

To be considered for Award of Work process, bidder should submit their bids in accordance with the requirements contained in this document.

THSTI reserves the right to update, amend and supplement the information in this document including the qualification process before the last date and time up to the receipt of bids.

This document is non-transferable.

THSTI reserves the right, without assigning any reasons, to abort the whole process.

2. Need for LIMS:

The **Bioassay laboratory** is working as per the requirements of ISO 17025: 2017 standard and has filed for NABL accreditation. Instrument calibration, maintenance and preventive maintenance need to be traced (optional Laboratory Execution System with digitized SOP driving the workflow)

Workflow

1. Sample receipt from clinical sites
2. Sample accessioning/ Bar coding
3. Sample storage
4. Sample retrieval for respective assay
5. Performing assay
6. Results
7. Reporting to the sample sender

Analytical Instruments to be integrated

1. Thermal Cycler (PCR)
2. Real Time PCR
3. FACS
5. ELISA Reader
6. ELISA Washer

New equipment may be added in future. The software should have the capacity to add new equipment in future.

3. The Selection Process:

The selection process of the bidder will comprise of the following steps:

3.1 Invitation for tender:

THSTI invites e-tender for selection of agency for implementation of LIMS software at THSTI, Faridabad. An advertisement in respect of this NIT(e-tender) has been published CPPP and also uploaded on the THSTI website, as per standard practice of Government of India. This document with key details of the project and response formats is made available on CPPP website and Institute website for participation by the all prospective bidders.

3.2 Pre-Bid Meeting:

To solicit prospective bidders' feedback, on specifications/terms of the Tender, a pre-bid meeting with all the prospective bidders is scheduled to be held on 19.10.2020 from 04.00 PM onwards. The venue of the meeting will be THSTI, Faridabad. Interested bidders can attend the same with a written statement of their queries. The

interested bidders can also join the meeting online, a link for which will be provided only to the vendors who will submit their request/queries via email to support@thsti.res.in copy to tushar.sharma@thsti.res.in latest by 19.10.2020 till 11:00 AM.

3.3 Notification of amendments:

As a result of the pre-bid meeting, if the NIT document requires any modification, suitable amendment to the NIT document will be issued and the same will form part of the NIT document. [Corrigendum/amendments etc., if any, will be notified only on the THSTI web site and CPPP website. No separate advertisement will be released for the same.](#) Prospective bidders are therefore advised to regularly visit these websites for any such updates.

3.4 Submission and Opening of online tenders

3.4.1 Under the two bid system, the bidders are required to submit their 'Technical bid' and 'Financial bid' online separately. All the documents related to technical bid (i.e. Eligibility criteria & Technical details) and financial bid should be uploaded online.

3.4.2 The 'Technical bid' submitted online should be supported by the following documents:

- a. Copy of application form along with documents relating to eligibility criterion (as per Form 1 to 13)
- b. Copy of Technical specification compliance sheet (Form 14).
- c. Copy of Complete Tender Document with each page duly signed and stamped
- d. Any other certificate or document essential to establish the qualification of the bidder as per the Pre-qualification criteria.

3.4.3 The 'Financial bid' should be submitted online as per prescribed format (Part C).

3.4.4 The Financial bid should be valid and open for acceptance for a period of 180 days from the date of opening of the technical bid.

3.5 Opening of Technical bid

Technical bid submitted online shall be opened on 06.11.2020 at 4:00PM at THSTI, Faridabad.

4. Opening of Price bid

The price bid of firms whose bids are found to be technically qualifying will be opened at a date and time to be decided by the competent authority.

5. Pre-qualification criteria and Evaluation of bids

The work will be awarded to the tenderer whose bid has been determined to be eligible and to be substantially responsive to the tender documents and who has offered the highest evaluated bid based on the technical marks and Financial marks obtained during the evaluation as stated under section 5.2 of this document.

5.1 Pre-Qualification criteria

5.1.1 Pre-qualification conditions:

Bidder must fulfill the following Pre-Qualification criteria and must individually provide the Pre-Qualification documents as documentary evidence:

5.1.1.1 The Bidder should be registered under the Companies Act, 1956, should have registered offices in India and should be in existence for at least last 5 years, as on 31st March 2020. The Bidder shall have valid GST and PAN number allotted by the respective authorities.

5.1.1.2 The Bidder shall not be banned/ blacklisted/ defaulter by any State or Central Government/ any other Government institutions in India for any reason as on last date of submission of the Bid. A declaration is required to be submitted by the bidders on their company letterhead duly signed by the authorized signatory of the company.

5.1.1.3 The bidder should have annual turnover of minimum Rs. 2 Crore and positive net worth in each of the past three financial years ending 31st March 2020. It may please be noted that “Annual Turnover” implies turnover from the following:

- a. LIMS application development and maintenance Services
- b. LIMS Facilities Management Services
- c. LIMS Support and Maintenance Services
- d. Turnover from LIMS Business

Details as per Form 6 along with audited financial statements to be attached.

5.1.1.4 Bidder should have at least 25 LIMS professionals on its rolls as of last date of submission of this bid. Certificate from HR head in this regard to be attached.

5.1.1.5 Bidder should have experience of successfully executing minimum 3 (three) LIMS projects in past five years. Further, the bidder should have executed project on LIMS implementation, costing either of the following, during the last five years ending last date of submission of the bid:

One similar order costing not less than INR 72 Lakhs.

Or

Two similar orders each costing not less than INR 45 Lakhs each.

Or

Three similar orders each costing not less than INR 36 Lakhs each.

Similar order means “Supply, Installation, Implementation and Maintenance of LIMS software, covering the Functional Requirements mentioned in this tender, in Central/State Government/PSU/Autonomous bodies or any government organization in India during last five years (comprising completed projects only)”. Documentary evidence, along with client contact details, Work

order, Purchase order and Completion certificate (Mandatory) from clients to be attached as per the formats given in this document.

5.1.1.6 Bidder should have ISO 9001 and (SEI) CMMI level 3 certifications. Copies of the Certificates signed and stamped by the authorized signatory of the Bidder to be attached.

5.1.1.7 Bidder shall be the OEM (Original Equipment Manufacturer) of the LIMS Solution.

5.1.1.8 Bidder, during past 7 (Seven) years, to be counted prior to bid due date should have successfully executed Enterprise LIMS Solution for at least 2 customers in Private or Government organizations where vaccine dosed samples are analyzed. Out of the two implementations, minimum one implementation should have involved integrating instruments and the lab in the process of / got NABL or ISO 17025 accreditation. Details to be furnished under Form 8 and/or Form9 along with necessary documentary proof.

5.1.1.9 The LIMS solution should have features complying with the requirements of international standards - ISO 17025:2017 for testing laboratories. Certificate to be attached.

5.1.1.10 The LIMS Solution (offered or its earlier version) Should be implemented by the OEM or its direct operations in India only. Consortiums are not allowed. Relevant documents of the implementation team, their experience should be provided along with the technical offer.

5.1.1.11 The bidder shall have an established support center in India to carry out implementation and after sales support activities for the offered LIMS solution. The bidder has to submit the list of support centers available in India. Use Form 5.

5.1.2 PROPOSAL EVALUATION PROCESS

Proposals will be evaluated by a designated Committee duly appointed by the Competent Authority, THSTI, Faridabad. THSTI or such other authority designated by THSTI, as the case may be, is also referred to herein as the Committee of Experts/LIMS Evaluation committee (or “the Committee”).

THSTI has the right to appoint any individual / organization as an expert member of this committee as long as the particular person does not have any conflict of interest in the bidding/evaluation process.

THSTI has the right to share the contents of the proposals or bids with the experts or consultants appointed for the purpose of evaluation of the bids, as the case may be.

Evaluations of bids will be only on the basis of information provided by the bidders in the proposals, Site Visit evaluation reports which is to be made by the LIMS evaluation committee, or any additional information provided by the bidders against specific requests for clarifications sent by THSTI during the evaluation process. All the documents submitted against the tender should stand correct and valid at the time of this evaluation. Any deviation in the documents submitted must be explicitly brought under the notice of THSTI.

5.2 Evaluation of bids:

A two stage screening process will be adopted for evaluation of the bids received from the bidders as given below:-

5.2.1 First Stage Screening Process:-

The bid submitted by the prospective bidders in response to this e-tender will be evaluated against the pre-qualification conditions specified in the tender. Based on this evaluation, the potential bidders who meet the qualifying criteria will be short listed for further consideration by the LIMS Evaluation Committee. The pre-qualification conditions have been formulated to assess the competence and capability of the potential bidding firms to meet the requirements of THSTI for providing the LIMS software Solution services.

5.2.2 The process of evaluation as per Quality & Cost Basis Selection (QCBS)

The bidders who qualify the first stage screening process will be invited for presentation/Live Demo of the offered product to the LIMS Evaluation Committee of THSTI. Further, site visit to their offices and place of LIMS implementation, as claimed by the bidders, may be carried out by the LIMS Evaluation Committee. The screening of the bidders will be performed based on the documentary proofs attached with the technical bids and the site visit report prepared by the committee.

As a result of the above screening process, the name of the bidders who are recommended by the LIMS evaluation committee will be declared as the technically qualified bidders.

THSTI shall shortlist all the agencies/Bidders who secure the minimum cut off of 75% (Seventy Five Percent) on aggregate basis. However, THSTI has an absolute right to modify the threshold marks for qualifying technical evaluation.

The technical evaluation carried out by THSTI management shall be final in all aspects.

The financial proposals of only technically shortlisted bidder will be opened and will be ranked in terms of their total evaluated cost.

Technical Points will be awarded to the bidder based on their technical evaluation score. Technical Points will be evaluated as below

- If technical score scored by A, B & C are 90, 81 & 72 respectively, the Technical points scored by A, B & C will be 90, 81 & 72 respectively.

| Firm | Technical Score | Technical Points |
|------|-----------------|------------------|
| A | 90 | 90 |
| B | 81 | 81 |
| C | 72 | 72 |

In case of financial bid, firm with lowest fee/price will be given 100 as Financial Point and Financial Points of other two bidders will be calculated with formula as below:

- $\text{Lowest Price/Individual Price} \times 100$. If price quoted by B is 90 (lowest one) and price quoted by A and C are 120 and 96 resp., then Financial Point of B = 100 and Financial Point of A = $90/120 \times 100 = 75$ and Financial point of C = $90/96 \times 100 = 93.75$.

| Firm | Financial Score | Financial Points |
|------|-----------------|------------------|
| A | 120 | 75 |
| B | 90 | 100 |
| C | 96 | 93.75 |

For evaluating the Total Points, quality and cost basis selection shall be applied with below mentioned weights

| Parameters | Weights |
|------------------|---------|
| Technical Points | 70% |
| Financial Points | 30% |
| Total | 100% |

The Total Points shall be calculated using the formula as (Technical Point x 0.70 + Price Pont x 0.30)

The proposals/Bids securing the highest Total Points in the above evaluation will be ranked as H-1 followed by the proposals securing lesser marks as H2, H3, etc. Illustration of the same is as below

| Firm | Technical Points (T) | Financial Points (F) | Total Points (0.7XT+0.3XF) | Ranking |
|------|----------------------|----------------------|----------------------------|---------|
| A | 90 | 75 | 85.50 | H2 |
| B | 81 | 100 | 86.70 | H1 |
| C | 72 | 93.75 | 78.53 | H3 |

The firm with the Highest ranking (H1) shall be recommended for engagement. In the scenario of a tie in Total Points, firm with higher Technical points will be ranked higher. In scenario of tie up of both Total Points and Technical Points, Firm with higher presentation Points will be ranked higher. In case there is a tie in each of Total Points, Technical Points, Financial Points and Presentation Points, fresh financial bids shall be invited.

A maximum of 100 points will be allocated for the technical proposal for the different parameters listed in the technical proposal requirements for LIMS solution, as per following distribution.

| Parameter | Points | Brief Description |
|-----------|--------|-------------------|
|-----------|--------|-------------------|

| | | |
|---|-------------------|---|
| Solution fitment | 50 points | Assessment of the offered modules of product (Max Marks 20) + Marks based on the live demo/presentation of the product (Max Marks 30) |
| Site visit feedback | 25 points | |
| Specific experience and evaluation criterion for project team | 25 points | As per Evaluation criterion specified |
| Total Score | 100 points | |

Out of a possible 100 points, a proposed LIMS solution should score a minimum of 75 points to qualify for the Financial evaluation.

Solution Fitment Maximum Marks 50

1) Bidders assessment of the offered modules of product (Max Marks 20)

THSTI is looking for a solution, which would need minimum or no extra development, if any, the solution proposed will be rated accordingly – the solution, which need less customization being rated better than the others.

The response for the solution fitment will be scored based on the five types of responses – readily available or standards, work around needs customization, not available but met through third party tool, not available/not proposed or addressed.

| Compliance | Guidelines | Response | Marks |
|-------------------|--|-----------------|--------------|
| Standard | The specific requirement or process is a standard feature with the offered LIMS solution | S | 2 |
| Work Around | The requirement can be realized by modifying the process but without any development | W | 1.5 |
| Customization | The requirement can be realized by writing a set of software codes | C | 1 |
| Third Party | The specific requirement is realized through a third party tools | T | .5 |
| Not Possible | The requirement is not possible or not part of the proposed LIMS solution | N | 0 |

The appropriate response for each of the following module should be made as per **Form 14, Functional Compliance** of the technical bid. Based on the documents describing the functionality and capabilities of the software, submitted in technical bid by the bidder and taking into consideration any clarification/demonstration made during the Live Demo, the THSTI's Committee of Experts will evaluate the LIMS solution as per the matrix below:

| S. No | Requirements as per the technical specifications described under section 1.1 to 1.11 under Part B of this document | Response S/W/C/T/N. | Marks obtained (Max 20) |
|-------|--|---------------------|-------------------------|
| 1. | Sample Login (Registration) | | |
| 2. | Sample Receipt: the process of confirming physical receipt of Sample in Lab. | | |
| 3. | Test Assignment, Result Entry, Calculations and comparison with specifications | | |
| 4. | Authorization and Publishing of Results | | |
| 5. | Security and Audit Trail | | |
| 6. | Reports generation and Search Facility | | |
| 7. | Instrument Maintenance & Calibration | | |
| 8. | Inventory Management for Reagents, Consumables and Spares | | |
| 9. | Regulatory Compliance | | |
| 10. | Location Management and Lab Execution System/ELN | | |

2. Marks based on the live demo of the product (Max Marks 30)

The prospective bidders will make a Live Demo presentation of their LIMS Solution covering the listed requirements. Based on that, the evaluation committee will give befitting marks for each of the following functionality of their LIMS Solution.

| S.no. | Functionality/Feature | Max Marks (30) |
|-------|---|----------------|
| 1 | Logging in of Scheduled and Un-scheduled Samples | 1 |
| 2 | Receipt of Samples using Bar-code reader | 1 |
| 3 | Display / Alerts of Samples logged in but not received | 1 |
| 4 | Result entry | 1 |
| 5 | Validating of Results against Specifications | 1 |
| 6 | Authorization of Results | 1 |
| 7 | Search facility for Samples as per user requirement | 1 |
| 8 | Certificate of Quality generation covering parameters as per format provided | 1 |
| 9 | Integration with at least one balance (to be brought by vendor) and example result file capture | 1 |
| 10 | Integration capability with regular used lab Instruments like GC, HPLC, ICP. | 1 |
| 11 | System audit trail encompassing exhaustive user activities | 1 |
| 12 | Super admin control | 1 |
| 13 | User Dashboard | 1 |
| 14 | Functionality with the mobile app. | 1 |
| 15 | Proof of live system running as per the claims made in the documents. | 1 |
| 16 | Generation of flexible reports based on values provided by the user | 2 |
| 17 | Capability of adding desired input fields in all the Master forms | 2 |
| 18 | Fulfilment of requirements through readily available standard reports which can be exported into other formats like pdf, excel, csv, etc. | 2 |
| 19 | Functionality provided for System Administrator to create new reports from the software in order to address any future requirement | 2 |
| 20 | Customizable Workflow Management | 2 |
| 21 | Domain knowledge of the Project Manager who shall be demonstrating the system | 5 |

3. Evaluation Criterion for Site Visit: Maximum Marks 25

During the site visit, the committee members will take the user feedback on the following benchmark/preferences and a rating for the response from the user will be marked. Based on that the final evaluation of the site visit will be done and will abide to the bidder.

| Sr.no. | Evaluation Criterion considering general scenarios | Benchmark / Preferences | Rating Scale |
|--------|--|---|--------------|
| 1 | Resolution of Support call | 1 mark for call resolution within 1 working day | 0 or 1 |
| 2 | Any incident of data loss or data breach | 1 mark for no such incident | 0 or 1 |

| | | | |
|----|---|---|----------------|
| 3 | System manageability from the Lab In charge/Lab Manager/ Lab Director's point of view | Recommendation | between 0 to 3 |
| 4 | Sample Login (Registration) | Whether functional as per the THSTI's requirement | between 0 to 2 |
| 5 | Sample Receipt: the process of confirming physical receipt of Sample in Lab. | Whether functional as per the THSTI's requirement | between 0 to 2 |
| 6 | Test Assignment, Result Entry, Calculations and comparison with specifications | Whether functional as per the THSTI's requirement | between 0 to 2 |
| 7 | Authorization and Publishing of Results | Whether functional as per the THSTI's requirement | between 0 to 2 |
| 8 | Security and Audit Trail | Whether functional as per the THSTI's requirement | between 0 to 2 |
| 9 | Reports generation and Search Facility | Whether functional as per the THSTI's requirement | between 0 to 2 |
| 10 | Instrument Maintenance & Calibration | Whether functional as per the THSTI's requirement | between 0 to 2 |
| 11 | Inventory Management for Reagents, Consumables and Spares | Whether functional as per the THSTI's requirement | between 0 to 2 |
| 12 | Regulatory Compliance | Whether functional as per the THSTI's requirement | between 0 to 2 |
| 13 | Location Management and Lab Execution System/ELN | Whether functional as per the THSTI's requirement | between 0 to 2 |

4. Specific experience and evaluation criterion for project team (Maximum Marks 100. To be normalized for 25 Marks)

| Sr. No. | Description of Criteria / Sub-Criteria | Max. Marks |
|---------|---|------------|
| (i) | Number of similar LIMS Solutions completed during last five years as on the due date for submission of bids. [Health Sector : 4 Marks for each project, Other than Health Sector: 2 marks for each project] | 20 |
| (ii) | Adequacy of the proposed methodology and work plan in response to the terms of reference | 30 |
| (a) | Adequacy of Technical methodology & work plan | 15 |
| (b) | Adequacy of overall organization & staffing to demonstrate ability to deliver project of described scale | 15 |
| (iii) | Key professional staff: Qualification & competency for the assignment/job. Qualifications and competency of each of the key professional will be evaluated separately. The resume of the below mentioned team is to be attached with the technical bids. | 40 |

| | | |
|-----|---|------------|
| (a) | Project Manager -min. experience of 10 years | 20 |
| (b) | Team Leader (Functional/Scientific) – min. experience of 5 years | 10 |
| (c) | Team Leader (Software) – min. experience of 5 years | 10 |
| | For evaluation of each of the key professionals above, the following sub-criteria shall be followed: | |
| | <i>i Educational qualifications(Masters Degree in relevant domain)</i> | 20% |
| | <i>ii Adequacy for the assignment/job (Experience in carrying out similar assignments) Six projects 10% each for Project Manager and Three projects 20% each for Team Leaders</i> | 60% |
| | <i>iii Relevant certification(Relevant technology specific certification for Team Leaders and Project Management based certification for Project Manager)</i> | 20% |
| | Total Marks - (i) + (ii) + (iii) + (iv) | 100 |

6. Scope of Work, Processes and Functional Specification

The objective behind implementation of the proposed LIMS Solution is described in “Part B, Addendum to e-TENDER (Schedule of Requirement and Process Specification)”, placed at the later section of this document. **Together, the Functional and Technical sections of Part B forms the detailed Scope of Work.**

The processes and specification are only indicative in nature and THSTI reserves the right to add, modify or delete any of the equipment/requirement which are identified at a later stage. Also, suggestion for inclusion, modification or deletion of any process as specified here under may also be submitted by the prospective bidders as per their experience and expertise so as to make the process specification more generic and comprehensive.

All the prospective bidders are requested to kindly study and analyze the specification carefully before submitting their bids. The broad scope of the project envisages a complete turnkey solution which includes the following

| | |
|---|--|
| 1 | System Requirement Study |
| 2 | To-be Business Process Documentation and System |
| 3 | Design and Development |
| 4 | Testing |
| 5 | Data Digitization and Migration |
| 6 | Hands on Training |
| 7 | Go Live and deputation of one technical staff at THSTI premises for 3 months |

| | |
|---|--|
| 7 | Change Management |
| 8 | Warranty Maintenance support to LIMS for 3 years |

The proposed LIMS solution should be deployable in multiple locations (if required), should use Web technology and should be scalable and flexible. The solution should be customized according to the functional requirements of THSTI and should be able to cater to the needs of **5 concurrent users** with provision for future expansion. The solution should be such that it has flexibility of adding more modules as per functionality and requirement of THSTI.

From functional point of view, the project should comprise of the following modules:

1. Sample Login (Registration)
2. Sample Receipt: the process of confirming physical receipt of Sample in Lab.
3. Test Assignment, Result Entry, Calculations and comparison with specifications
4. Authorization and Publishing of Results
5. Security and Audit Trail
6. Reports and Search Facility
7. Instrument Maintenance & Calibration
8. Training Records of Analysts
9. Inventory Management for Reagents, Consumables and Spares
10. Regulatory Compliance

7. Procedure for submission of online bids and EMD

- 7.1 The bidders are advised to read the NIT document carefully before submitting their bids. It shall be deemed that the bid has been submitted by the bidder after reading complete NIT document and full understanding of its implications.
- 7.2 The procurement will be carried out through submission of online bids only. No offer in physical form will be accepted and any such offer if received by THSTI will be out rightly rejected. Tender documents can be downloaded from CPPP website i.e.: www.eprocure.gov.in. or Institute website: www.thsti.res.in. Bids complete in all respect as per NIT (Technical and Financial) are to be uploaded on CPPP website i.e.: www.eprocure.gov.in. The bidders should have a valid digital signature certificate (Class'II or Class'III) issued by any of the valid Certifying Authorities to participate in the online tender. The bids shall be uploaded in electronic form only on www.eprocure.gov.in website. Before submission of bids, the bidders are requested to kindly read the "Guidelines to bidders on CPPP's e-procurement module" available at the end of this tender document.
- 7.3 The payments for Tender Fee and Tender EMD will be made by using online payment portal. The approved modes of payments are Net Banking, Debit Card, Credit Card and UPI, failing which the bid will be rejected.

7.4 Print Final Payment Receipts and include the softcopy of final payment receipt in your technical bid.

Following are the steps for online payment:

7.4.1 Visit on Notification à Tender Page on THSTI Website (<https://thsti.res.in/notification-tender.php>) & click on Pay button beside the tender;

7.4.2 Fill Vendor Details i.e. Supplier Name, PAN No., Contact Person, Email Id, Mobile No. and click on “Continue to Payment” button;

7.4.3 Confirm Payment details after carefully examining the auto-fetched tender details and the filled information and click “Confirm and Redirect” to proceed to the payment gateway. The Email id and Mobile number will be used for the payment confirmation at the later stage;

7.4.4 Check Redirect to Payment Portal;

7.4.5 Make payment using any payment mode (i.e. Net Banking, Debit Card, Credit Card or UPI); fill in the mobile number, email id to receive email and SMS notification for your payment and click on “Proceed Now”;

7.4.6 Redirect to Payment Status;

7.4.7 Provisional Transaction Receipt (if payment has not failed);

7.4.8 See your payment history by providing your details;

7.5 The bid securities of unsuccessful tenderer will be returned within 30 days after the finalization of the tender & award of the contract . No interim inquiry or request in between shall be entertained in this regard.

7.6 The bid Security of the successful bidder shall be returned upon receipt of desired Performance Security and upon its verification.

7.7 Withdrawal or modification of offer by the tenderer during the interval between the deadline for submission of bids and expiry of the period of bid validity will not be permitted and will result in the forfeiture of its bid security.

7.8 The bid should be submitted containing all the relevant Documents. Using the relevant forms given in this document, bidders are required to submit the following details along with relevant documentary proofs in claim of their eligibility:

| Sr. No | Criteria | Detail | Supporting document required | Compliance (Yes/No) along with page numbers supporting document |
|--------|-------------------------|------------------------------|------------------------------|---|
| 01 | Bidder's Profile | Information about the Bidder | Form No. 5 | |

| | | | | |
|----|---------------------------|---|---|--|
| 02 | Financial Strength | <p>The bidder should have annual turnover of minimum Rs 2 crore and positive net worth in each of the past three financial years ending 31st March 2020. It may please be noted that “Annual Turnover” implies turnover from the following:</p> <p>LIMS application development and maintenance Services</p> <p>LIMS Facilities Management Services</p> <p>LIMS Support and Maintenance Services</p> <p>Turnover from LIMS Business</p> | Form No. 6{ Certificate from statutory authority for declaring turnover and net worth } | |
| 03 | Manpower Strength | Bidder should have at least 25 LIMS professionals on its rolls as of last date of submission of this TENDER. | Form No. 7{ Certificate from HR Head } | |
| 04 | Project Experience | <p>Bidder should have experience of successfully executing minimum five LIMS projects in past five years. Further, the bidder should have executed project on LIMS implementation, costing either of the following, during the last five years ending 31st March, 2019:</p> <ul style="list-style-type: none"> One similar order costing not less than INR 72 Lakhs. <p>Or</p> <ul style="list-style-type: none"> Two similar orders each costing not less than INR 54 Lakhs each. <p>Or</p> <ul style="list-style-type: none"> Three similar orders each costing not less than INR 45 Lakhs each. | Documentary evidence as per Form 8 and 9{ copy of work completion certificate to be attached} | |
| | | Bidder, during past 7 (Seven) years, to be counted prior to bid due date should have successfully executed Enterprise LIMS Solution for at least 2 customers in Private or Government | Documentary evidence as per Form 8 and 9{ copy of work completion certificate to be | |

| | | | | |
|----|-----------------------|---|---|--|
| | | organizations where vaccine dosed samples are analyzed. Out of the two implementations, minimum one implementation should have involved integrating instruments and the lab in the process of / got NABL or ISO 17025 accreditation | attached} | |
| 05 | Certification | <p>Bidder should have ISO 9001 and (SEI) CMMI level 3 certifications.</p> <p>The LIMS solution should have features complying with the requirements of international standards - ISO 17025:2017 for testing laboratories.</p> | Copies of the Certificates signed and stamped by the authorized signatory of the Bidder to be attached. | |
| 06 | Declaration | The bidder shall have an established support center in India to carry out implementation and after sales support activities for the offered LIMS solution. The bidder has to submit the list of support centers available in India. | Declaration, details of the contact person(s) and their experience details | |
| 07 | Product Manual | The product manuals should be exhaustive and should be able to demonstrate the capabilities of the product against the software specific requirements stated in this tender document | | |

7.9 The technical bid should also address/contain the following points/documents:

1. Methodology and approach for implementation of the solution in terms of process design, solution configuration, deliverables, formats for deliverables, the project standards, the acceptance criteria for the deliverables, testing strategy etc.
2. Project Plan, structure and team – the project timelines, resource loading, and expertise deployed for the project.
3. Method and Support and maintenance ticketing system along with call resolution time.
4. Certifications: CMMI Level 3, ISO 17025:2017
5. Forms 1 to 14.
6. All the documents in support of point 1 to 25 of Form 14.
7. Resume and certificates of the Project Manager and the key professionals on behalf of which the marking will be given.
8. Product manual

8. Clarifications on bid:

To assist evaluation and comparison of the tender, the THSTI, NCR BIOTECH SCIENCE CLUSTER may at its discretion ask the bidder for clarification on the submitted bids. The clarification and response from bidder shall be in writing / email.

9. Cancelling the tender:

The Executive Director, THSTI reserves the right to cancel/reject the TENDER and any or all the bids without assigning any reason whatsoever at any time/stage.

10. Performance Security

- 10.1 The contractor will be required to furnish performance security as per prescribed format for an amount equal to 10% of the value of the work order in the form of CDR/FDR//Bank guarantee (of nationalized/ Scheduled Bank in a standard format) within two weeks from the date of signing/execution of a work agreement. The performance security should remain valid for a minimum period of 44 months plus sixty days claim period from the date of acceptance of the work order.
- 10.2 The performance security will be released on expiry of the warranty period of work (36 Months) subject to satisfactory fulfillment of its obligations by the contractor under the work.
- 10.3 Failure of the successful contractor to lodge the required Bank Guarantee shall constitute sufficient grounds for the annulment of the Award and forfeiture of the Bid Security, in such event THSTI, Faridabad shall Award the work order to the next highest evaluated tenderer or, if there are no other tenderer, call for new bids.
- 10.4 In the event of breach of contract by the contractor, the performance security will liable to be forfeited by THSTI, Faridabad

11. Project Timelines

The duration for completion of the entire scope of work is **8 months from the date of acceptance of the work order.**

| S.N. | Activity Description | Deliverables | Timelines |
|------|----------------------------------|--|----------------------------|
| 1 | Visit to THSTI's designated lab. | Visit Report and key observations for the purpose of implementing LIMS | Project Start Date+ 5 days |
| 2 | Inception meeting: | Inception Report | Project Start Date+10 days |
| 3 | System Requirement Study: | System Requirement Study (SRS) Report | Project Start Date+30 days |

| | | | |
|----|--|---|---|
| 4 | To-be Business Process Documentation and System Design | System Design Document (SDD) | Project Start Date+40 days |
| 5 | LIMS Design and Development: duly incorporated | Module-wise report on development of LIMS and Ready to Test LIMS software | Project Start Date+120 days |
| 6 | LIMS Testing: | Testing Approach and Plan. All the software licenses, keys, administrative passwords of the system/database etc. | Within 30 days of delivering the complete module as per 5 above |
| 7 | Data Digitization and Migration | Report on completion of data digitation and migration to LIMS | Within three weeks of final testing and handing over of LIMS to THSTI |
| 8 | Hands on Training on use of LIMS | Training Manual and end-user manual and Training completion report | Within three weeks of final testing and handing over of LIMS to THSTI |
| 9 | Go Live | Handing over/delivery document which comprises of necessary passwords, keys and the other deliverables as mentioned in the previous stages of the deployment. 3 Months deputation of 1 technical staff at THSTI's premises for the purpose of hand holding of the users during the initial phases. All the expenses incurred regarding travel, lodging etc. will be borne by the successful bidder. | Within one week of completion of training |
| 10 | Change Management: | Change Management Strategy and Plan | Within three weeks of going live |
| 11 | Final Acceptance Certificate | THSTI will provide the Final Acceptance certificate mentioning the date of issuance. | Within five weeks of going live |
| 12 | Warranty Maintenance support to LIMS for 3 years | | Three years from issuance of Final Acceptance |

| | | | |
|--|--|--|-------------|
| | | | Certificate |
|--|--|--|-------------|

12. Payment Milestones

The following milestones are associated with the respective project activities as described under section 12 “Project Timelines”.

| S.No. | Activity | Milestone # | Payment percentage |
|-------|--|-------------|--------------------|
| 1 | Visit to THSTI's designated lab. | Milestone 1 | 10 |
| 2 | Inception meeting | | |
| 3 | System Requirement Study | | |
| 4 | To-be Business Process Documentation and System | | |
| 5 | LIMS Design and Development | Milestone 2 | 20 |
| 6 | LIMS Testing | Milestone 3 | 20 |
| 7 | Data Digitization and Migration | | |
| 8 | Hands on Training on use of LIMS | | |
| 11 | Go-Live, Change Management, Deputation of one technical staff for 3 months at THSTI and issuance of Final Acceptance Certificate by THSTI. | Milestone 4 | 20 |
| 12 | Warranty Maintenance support to LIMS for 1 st year | Milestone 5 | 10 |
| 13 | Warranty Maintenance support to LIMS for 2nd year | Milestone 6 | 10 |
| 14 | Warranty Maintenance support to LIMS for 3rd year | Milestone 7 | 10 |

THSTI shall release the payment within 30 Days from the date of bill submission provided that the respective milestone is reached and has been agreed and accepted by THSTI though.

13. Time and Extension for Delay

13.1 If in the opinion of the THSTI the works is delayed due to:

- a) Force majeure.
- b) Reasons of civil commotion, location combination of workers on strike or lock-out affecting any of the building trades.
- c) In consequence of the bidder for not having received in due time necessary instructions from the THSTI for which he has specifically applied in writing.
- d) Reasons of THSTI's instruction

THSTI shall make a fair and reasonable extension of time for completion of the contract. Then upon the happenings of any such event causing delay, the bidder shall immediately give notice thereof in writing to the THSTI but shall nevertheless use constantly his best endeavor's to prevent or make good the delay and shall do all that may be reasonably required to the satisfaction of THSTI to proceed with the works.

13.2 Request for rescheduling of date of completion and extension of time, to be eligible for consideration, shall be made by the successful bidder in writing immediately after the happenings of the event causing delay. The successful bidder may also, if practicable, indicate in such a request the period for which extension is desired.

13.3 In such case, the THSTI may give a fair and reasonable extension of time and reschedule the completion date. Such extension shall be communicated to the success bidder by THSTI in writing within 1 month of the date of receipt of such a request. Non-application by the successful bidder for extension of time shall not be a bar for giving a fair and reasonable extension by THSTI and this shall be binding on the successful bidder.

13.4 In case of unforeseeable causes beyond the control and without the fault or negligence of the bidder, which has made the Project bound to be delayed by any duration (in number of days/weeks), the either party may submit their request for exemptions. The Competent Authorities of THSTI may allow exemptions/imposition of penal action upon the recommendation of the Committee of Experts/LIMS Committee. The decision of the Competent Authority of THSTI shall be final and binding.

14. Compensation for Delay

Time is the essence of the contract. The time allowed for the work shall be strictly followed otherwise the Contractor shall be liable to pay compensation at the rate of 0.5 % of the ordered value of the work per week of delay or part thereof on the part of the successful bidder subject to a maximum of 5% of the total ordered value. The decision of THSTI about the delay shall final and binding.

15. Guarantee Clause

The bidder shall guarantee that the complete project including all the material and components supplied and installed by him shall be free from defects.

The bugs, defects and any shortcomings found in the system shall be removed at no extra cost. The period of the warranty shall be (36) thirty six months from the date of handing over the complete project/installations to THSTI. During this period any or all components found to be defective shall be rectified free of cost.

If the defects/bugs are not removed within a reasonable time the THSTI may arrange to do at the bidder's risk and cost, without prejudice to any other rights.

After Sales Service: After sales service should be made available during the normal office hours on all the working days. Complaints should be attended promptly and properly within 24 hrs. The service should be provided directly by the bidder or his authorized agent whose details shall be provided to the THSTI/consignee within one month from the date of award of contract. Any cost incurred by THSTI due to non-rectification of the

complain which THSTI pays to any 3rd party during the warranty period will be deducted from the Performance Security Deposit submitted by the bidder.

16. Price Fall Clause

If at any time during the validity of the work, the successful bidder executed such similar nature's work with same specifications and requirements as stipulated in this tender enquiry, to any other organization at a price lower than the price quoted under this contract, he shall forthwith reduce the price payable under this tender for services being rendered from the date of coming into force of such reduction, the price of shall stand correspondingly reduced.

17. Abnormally Low Bids

An Abnormally Low Bid is one where the Bid price in combination with other constituent elements of the Bid appears unreasonably low to the extent that the Bid price raises material concerns as to the capability of the Bidder to perform the Contract for the offered bid price.

In the event of identification of a potentially Abnormally Low Bid, THSTI shall seek written clarifications from the Bidder, including detailed price analyses of its Bid price in relation to the subject matter of the contract, scope, proposed methodology, schedule, allocation of risks and responsibilities and any other requirements of the bidding document. After evaluation of the price analyses, in the event that THSTI determines that the Bidder has failed to demonstrate its capability to perform the Contract for the offered Bid Price, THSTI shall reject the Bid.

18. Termination

Being a standing offer, the work can be terminated from either side by serving one month's notice to the other party. However, all the order placed before the date of serving of such notice will be valid and binding on both the parties. Further, the orders placed under the work can also be terminated individually and the same will not lead to automatic termination of work itself unless so specified.

Termination of work order

Notwithstanding anything elsewhere provided herein and in addition to any other right or remedy available to THSTI under the work or otherwise including right of THSTI to claim compensation for delay, THSTI may, without prejudice to his right against successful bidder in respect of any delay, bad workmanship or otherwise or to any claims for damage in respect of any breaches of the contract and without prejudice to any rights or remedies under any of the provisions of this work or otherwise and whether the date for completion has or has not elapsed by intimation in writing, absolutely determine and terminate the Contract.

Default or failure by the successful bidder in any of the under mentioned cases, including but not limited to the following shall be the basis of taking action under this clause of the contract.

18.1 Failure to provide at the job site, sufficient manpower, material, equipment, software, and / or facilities, required for the proper and / or due execution of the work or any part thereof:

18.2 Failure to execute the work or any of them in accordance with the contract.

18.3 Disobedience of any order or instruction of the officer appointed by THSTI.

18.4 Negligence in carrying out the work or carrying out of work found to be unsatisfactory by the officer appointed by THSTI.

18.5 Abandonment of the works or any part thereof.

18.6 If the Contractor misconduct in any manner.

18.7 Delay in execution of work, which in opinion of THSTI shall delay the completion of work beyond the stipulated date of completion.

18.8 Distress, execution, or other legal process being levied on or upon any of the Contractors goods and /or assets.

18.9 Death of Contractor (if an individual)

18.10 If the Contractor or any person employed by him shall make or offer for any purpose connected with the contract any gift, gratuity, royalty, commission, gratification or other inducement (whether money or in any other form) to any employee or agent to THSTI.

The decision of the Executive Director, THSTI as to whether any of the events/ contingencies mentioned in previously mentioned clauses entitling THSTI to terminate the contract has occurred shall be final and binding upon the Contractor. The jobs left however by the successful bidder shall be got done at his risk and cost through the other agencies and the contract shall be determined accordingly.

19. Force Majeure

The right of the contractor to proceed with the work shall not be terminated because of any delay in the completion of the work due to unforeseeable causes beyond the control and without the fault or negligence of the contractor, including but not limited to acts of god, or of the public enemy, restraints of a sovereign state, floods, unusual severe weather conditions

20. Arbitration

Any claim, dispute or difference arising out of or in connection with this agreement and which cannot be settled by mutual consultations, shall be referred to sole Arbitration or an Arbitrator to be appointed by mutual consultations. The award of the Arbitrator shall be final and binding between the parties as per the terms and conditions of the Agreement to be executed on award of contract. The Arbitration proceeding shall be governed by the Arbitration and Conciliation Ordinance dated 26th March, 1996 and shall be conducted in Haryana.

Technical Manager (IT)

Bid Formats / Forms

Form-1: Bid Submission Form

(to be submitted on the letter head of the bidder)

To

The Executive Director,
Translational Health Science and Technology Institute,
NCR BIOTECH SCIENCE CLUSTER,
3rd Milestone, Faridabad-Gurgaon Expressway,
PO Box No. 04,
Faridabad - 121 001, Haryana (NCR Delhi), India
Phone: 91 129 2876493

Subject: Submission of e-TENDER for "Selection of Agency for designing, developing, configuring, implementing, integrating and commissioning of Laboratory Information Management System software at THSTI, NCR- Biotech Science Cluster, Faridabad".

Dear Sir/Madam,

We, the undersigned, offer to provide services to THSTI, NCR BIOTECH SCIENCE CLUSTER activities for providing LIMS Solution in response to your notice inviting tender dated....., we are hereby submitting our bid, which includes all the relevant Pre-Qualification Documents, technical compliance sheet along with all the requirement as mentioned under section 7.9.

We hereby further declare that all the information and statements made in this TENDER are true. We also undertake that any misinterpretation w.r.t NIT document may lead to disqualification and rejection of our bid. We also understand that you are not bound to accept any proposal you receive.

Yours faithfully,

Authorized signature *(in full and initials)*

Name and designation of the signatory

Name of the Firm

Business address

Office seal.....

Place.....

Date

Form-2: Bidder’s Authorization Certificate

(to be submitted on the letter head of bidder)

To
The Executive Director,
Translational Health Science and Technology Institute,
NCR BIOTECH SCIENCE CLUSTER,
3rd Milestone, Faridabad-Gurgaon Expressway,
PO Box No. 04,
Faridabad - 121 001
Haryana (NCR Delhi), India
Phone: 91 129 2876493

Dear Sir/Madam,

<Bidder’s Name>, **<Designation>** is hereby authorized to sign relevant documents on behalf of the company in dealing with Tender of reference (Tender No. & Date)

_____ He/She is also authorized to attend meetings, submit techno-commercial offer and negotiate on behalf of the company as may be required by the Institute in the course of processing this tender inquiry.

Yours faithfully,

Authorized signature *(in full and initials)*

Name and designation of the signatory

Name of the Firm

Business address

Office seal.....

Place.....

Date

Form-3: Self Declaration

(to be submitted on the letter head of the bidder)

Ref:

Date

To

The Executive Director,
Translational Health Science and Technology Institute,
NCR BIOTECH SCIENCE CLUSTER,
3rd Milestone, Faridabad-Gurgaon Expressway,
PO Box No. 04,
Faridabad - 121 001 Haryana (NCR Delhi), India
Phone: 91 129 2876493

Dear Sir/Madam,

In response to the TENDER No. _____ dated _____, as
Owner/Partner/Director _____ I/We hereby declare that our
Agency _____ is having unblemished past record and was not declared
ineligible for corrupt and fraudulent practices either indefinitely or for a particular period of time.

Further, I/we are not under a declaration of ineligibility/banned/ blacklisted/ fraud by any State or Central
Government/ any other Government institutions in India for any reason as on last date of submission of the Bid

We hereby extend our full guarantee and warranty as per terms and conditions of the aforementioned tender no. and
the contract for the services offered against this invitation for tender offer by the above firm. We also declare that the
offered products are not end-of-life products and the technologies used to create this product are not obsolete. We
also declare that the service and patches of the offered product will be available for minimum duration of 5 Years
from the last date of bid submission.

We understand that in case the above information is found incorrect, our TENDER will be rejected.

Yours faithfully,

Authorized signature (in full and initials)

Name and designation of the signatory

Name of the Firm

Business address

Office seal.....

Place.....

Date

Form-4: Certificate of Conformity

(to be submitted on the letter head of the bidder)

To
The Executive Director,
Translational Health Science and Technology Institute,
NCR BIOTECH SCIENCE CLUSTER,
3rd Milestone, Faridabad-Gurgaon Expressway,
PO Box No. 04,
Faridabad - 121 001
Haryana (NCR Delhi), India
Phone: 91 129 2876493

CERTIFICATE

This is to certify that, the services for THSTI for designing, developing, configuring, implementing, integrating, commissioning of Laboratory Information Management System software at THSTI, NCR- Biotech Science Cluster, Faridabad which I shall provide, if I am awarded with the work, are in conformity with the Scope of Work in the TENDER document.

Yours faithfully,

Authorized signature *(in full and initials)*

Name and designation of the signatory
.....

Name of the Firm

Business address

Office seal.....

Place.....

Date

Form-5: Bidder's Profile

| Sl. No. | Particulars | Details |
|---------|--|---------|
| 1. | Name of Bidder | |
| 2. | Incorporated as (State Sole Proprietor, Partnership, Private Limited or Limited Firm) | |
| 3. | Incorporation year | |
| 4. | Full address | |
| 5. | Name of the top executive with designation, telephone number, mobile number and Email | |
| 6. | GST No. | |
| 7. | PAN No. | |

Signature :

Name :

Designation :

SEAL :

Date :

Place :

Please attach necessary documents as per the above form.

Form-6: Financial Information

Please provide CA certified financial information of three last declared financial years.

| Particulars | 2017-18 | 2018-19 | 2019-20 |
|------------------------------|---------|---------|---------|
| Annual Turnover | | | |
| Net worth | | | |
| LIMS Implementation turnover | | | |

Note :-

- Please attach copies of relevant financial statements and audited accounts for the last five declared financial year*

Form 7: Manpower Details/Number of LIMS Professionals

(On Bidder's letter head)

To

The Executive Director,

Translational Health Science and Technology Institute,

NCR BIOTECH SCIENCE CLUSTER,

3rd Milestone, Faridabad-Gurgaon Expressway,

PO Box No. 04,

Faridabad - 121 001

Haryana (NCR Delhi), India

Phone: 91 129 2876493

Subject: Number of Professionals

Respected Sir/Mam,

This is to certify that <<Company Name>> have more than 25 LIMS professionals on its rolls as of Dated this Day of 2020

(Signature) (In the capacity of)

(Name)

Duly authorized to sign the TENDER Response for and on behalf of:

(Name and Address of Company) Seal / Stamp of bidder

Form-8: LIMS Solution Implementation Experience (General)

| Sl. No | Items | Details |
|----------------------------|---|---------|
| General Information | | |
| 1. | Customer Name | |
| 2. | Name of the contact person and contact details for the client of the assignment | |
| Project Details | | |
| 3. | Project Title | |
| 4. | Start Date: MM/YYYY End Date : MM/YYYY | |
| 5. | Current Status (work in progress/completed) | |
| 6. | Number of staff deployed in the assignment | |

Size of the project

| | | |
|-----|--|--|
| 7. | Total Cost of the project | |
| 8. | Period of contract | |
| 9. | Technologies Used | |
| 10. | Number of end users catered to by the system | |
| 12. | Any other information to be shared | |
| 13 | Documentary proof and details | |

Please attach the proof - Work Orders Completion Certificates, Certificates or Letter of Appointments etc. with the credential only

Form-9: LIMS Implementation Experience in Central/State Government, Government Institutions/PSU/Autonomous bodies etc.

| Sl. No | Items | Details |
|----------------------------|---|---------|
| General Information | | |
| 1. | Customer Name | |
| 2. | Name of the contact person and contact details for the client of the assignment | |
| Project Details | | |
| 3. | Project Title | |
| 4. | Start Date: MM/YYYY End Date : MM/YYYY | |
| 5. | Current Status (work in progress/completed) | |
| 6. | Number of staff deployed in the assignment | |

| | | |
|----------------------------|--|--|
| Size of the project | | |
| 7. | Total Cost of the project | |
| 8. | Period of contract | |
| 9. | Technologies Used | |
| 10. | Number of end users catered to by the system | |
| 12. | Any other information to be shared | |
| 13. | Documentary proof and details | |

Please attach the proof - Work Orders Completion Certificates, Certificates or Letter of Appointments etc. with the credential only

Form-10: Deviation Sheet

Deviation Sheet

| S. No. | Reference of the Clause No. of the TENDER | Text as written in TENDER | Deviation asked for by the bidder | Remarks |
|--------|---|---------------------------|-----------------------------------|---------|
| | | | | |
| | | | | |
| | | | | |
| | | | | |

Signed by _____

Name _____

Designation _____

Organization _____

Date & Place _____

Phone/Fax/Mobile/Email:

_____ Stamp &

Seal _____

Form-11: High Level Project Approach

Sl. No. **High Level Project Approach**

1 **Detailed Project approach must be tabulated here**

Form-12: Detailed Project Approach

| Sl. No. | Detailed Project Approach | Duration | No. of resources | On-site/Off-site |
|----------------|--|-----------------|-------------------------|-------------------------|
| | All the activities to be carried out under each scope should be listed here in bullet points | | | |
| | | | | |

Form-13: Expectations of the firm from THSTI NCR BIOTECH SCIENCE CLUSTER Team

| Sl. No. | Expectations from THSTI NCR BIOTECH SCIENCE CLUSTER |
|----------------|---|
| 1 | How can THSTI, NCR BIOTECH SCIENCE CLUSTER team aid in the project should be mentioned here |

Form-14: Technical Compliance Sheet

| S. No | Requirements as per the technical specifications described under section 1.1 to 1.11 under Part B of this document | Bidder shall state as: Fully Compliant/ Partially Compliant/ Non-Compliant. | Documentary proof attached including the screenshots from the live system Y/N |
|--------------|---|--|--|
| 1 | Sample Login (Registration) | | |
| 2 | Sample Receipt: the process of confirming physical receipt of Sample in Lab. | | |
| 3 | Test Assignment, Result Entry, Calculations and comparison with specifications | | |
| 4 | Authorization and Publishing of Results | | |
| 5 | Security and Audit Trail | | |
| 6 | Reports generation and Search Facility | | |
| 7 | Instrument Maintenance & Calibration | | |
| 8 | Inventory Management for Reagents, Consumables and Spares | | |
| 9 | Regulatory Compliance | | |
| 10 | Location Management and Lab Execution System/ELN | | |
| 11 | Logging in of Scheduled and Un-scheduled Samples | | |
| 12 | Receipt of Samples using Bar-code reader | | |
| 13 | Display / Alerts of Samples logged in but not received | | |
| 14 | Result entry | | |
| 15 | Validating of Results against Specifications | | |
| 16 | Authorization of Results | | |
| 17 | Search facility for Samples as per user requirement | | |
| 18 | Certificate of Quality generation covering parameters as per format provided | | |
| 19 | Integration with at least one balance (to be brought by vendor) and example result file capture | | |
| 20 | Integration capability with regular used lab Instruments like GC, HPLC, ICP. | | |
| 21 | System audit trail encompassing exhaustive user activities | | |
| 22 | Super admin control | | |
| 23 | User Dashboard | | |
| 24 | Functionality with the mobile app. | | |
| 25 | Proof of live system running as per the claims made in the documents. | | |

Part B
Addendum to the Tender

(Schedule of Requirement and Specification)

1. FUNCTIONAL:

Enlisted below are the broad functionalities / features which THSTI is looking for in the LIMS Solution proposed by the bidder. The bidder shall provide conformance for each of the points mentioned. The functionalities though broadly outlined here may be amended/elaborated by THSTI at the time of requirements study.

- A. Offered solution should be based on configurable system and customization should be restrictive. The configuration of the operations should be based on workflows which should be easily configurable by THSTI administration team.
- B. Minimum three workflows (Serological, Molecular, adhoc) for key assay types are to be configured.
- C. System should have mobile client by a dedicated APP from Google Play store, Apple I Store or Windows app store.
- D. Mobile client should facilitate and have instrument integration for seamless result gathering and review/authorize.
- E. Barcode should be mandatory in all modes of User Interface (Desktop, Web and Mobile app).

1.1 Sample Login (Registration)

Mandatory functionalities

- 1) In-built Auto-Scheduler module for Auto-Login of Scheduled or Routine Samples.
- 2) Feature in registration include:
 - a. Create new templates
 - b. Define fields for which samples are to be logged-in
 - c. Able to use any template for registration, creating barcodes, labels, pre-or post login of samples.
 - d. Define what test schedules are to be assigned by default for a specific registration template.
- 3) Manual Login feature for registration of Un-scheduled or Ad-hoc Samples, with facility to
- 4) Choose template for ease of login.
- 5) Login a sample from an existing sample. The new sample will contain the exact template information as the selected sample. This is to save time taken for logging in a Sample.
- 6) Sufficient fields / attributes to capture sample-related information in the LIMS system. (Minimum 20 fields based on current requirement scalable in future).
- 7) Additional custom fields (At least 15 as per current requirement) to capture any additional information against the Sample.
- 8) User-definable Name, data type and width for the additional custom fields.
- 9) Printing Barcode labels for any Sample that is logged in.
- 10) Login of samples before the actual sample time (Say before 30 minutes), so that the bar-coded label can be printed and kept ready for sample collection.

- 11) Configuration of flexible Barcode label formats to include any desired information pertaining to the Sample.
- 12) Creation of Sample Templates for ease of Sample Login: Pre-configuration of essential fields, and default values, default testing, etc. The objective of using templates is to reduce manual input to an absolute minimum and to ensure that required data is properly entered.
- 13) Creating and managing Sampling plan. A sampling plan is an outline of which Analyses will be conducted on which product and what will be the expected result or range of results (minimum and maximum specifications).
- 14) Selection of Analyses (Tests / Methods) while adding a sample plan to the scheduler.
- 15) Predicting sample quantity required based on the tests (Sample quantity for each test should be captured separately) associated with the sampling plan.
- 16) Unique identification for each state in the life-cycle right from registration to Receipt at Lab, Under-testing, Entry of results, Completion of testing, Authorization of results, Cancellation, On-Hold, Rejection, etc.
- 17) Date / time capturing at every state in the life-cycle of the Sample. For e.g. when sampled, sent to lab, received in lab.
- 18) Workflow creation, management for sample processing (login, allotting users, allotting instruments, triggering actions in the event of Off-Spec results, auto report generation, etc. It should be possible to create sub workflows and copies from one workflow. Every workflow should have provisions to attach relevant documents for the workflows. Workflows should control the lifecycles of the LIMS objects (entities like Samples, Analysis, Tests, Results, etc).
- 19) User definable Workflow allowing multiple stages or states like verification, activation, execution, review, approval, and final publishing. Each workflow step can involve notifications, printing of reports, electronic signatures, etc.
- 20) Ali-quoting and combining Ali-quoted Samples.
- 21) Select or de-select the tests or add new tests, by easy drag and drop options. Test should be identifiable by combination of 'short name of test' and method number.
- 22) Historical logging of scheduled. One time bulk logging of all scheduled samples from a unit by giving sample date and time. This option will be useful in case if the system is down at the time of auto login of unit samples. Also, if the server is down for longer period, the historical login will be useful in entering all the results which were recorded in hard copy or any other soft form (for data continuity in LIMS).

1.2 Sample Receipt: The process of confirming physical receipt of Sample in Lab.

Mandatory functionalities

- 1) Appropriate sample status change to indicate that Sample has been physically received in Lab.
- 2) Capture date / time of Sample Receipt in Lab. (By default, system date / time)
- 3) Provision to receive manually or using barcode reader.

- 4) Barcode label printing for the overall sample and/or for the containers as they are pre-logged or received.
- 5) Accept or Reject or Keep Sample on-hold at the time of Receipt.
- 6) Capture reason if rejected or kept on hold.
- 7) Email and application alert facility for the scheduled but not received samples after a pre-defined cutoff time. (say 60 minutes)

1.3 Test Assignment, Result Entry, Calculations and comparison with specifications

Mandatory functionalities

- 1) Addition of Tests to a Sample at any stage from login and prior to authorization.
- 2) Cancellations of Tests in a Sample before results are entered for the test.
- 3) Status field for each test assigned to a Sample, indicating whether results are yet to be entered, are entered for the first time, are modified or are approved.
- 4) Definition of one or many components of a test (For e.g. Distillation Test can have components - IBP and FBP).
- 5) Component level Result Entry.
- 6) Flexible Result entry option:
 - Single Sample – All Tests
 - One Test for range of Samples
 - Multiple Tests on range of Samples.

(Matrix form result entry for different samples v/s different parameters – Component may or may not be common for the samples).
- 7) Result entry through Manual mode or through Direct Instrument interfacing to LIMS. In case of auto-capturing test data from instrument, provision to filter and validate the test data by the concerned.
- 8) Auto transfer of results for samples containing multi components in a single command through direct instrument interfacing to LIMS. For e.g. LCMMSMS, ELISA reader, etc.
- 9) Results can be Numeric, Text, Alphanumeric, Calculated or Binary with provision for < or > symbol, they can be entered manually or selected through Menu or be derived as output of a calculation on other results and constants. Calculations are predefined mathematical routines which operate on the components to produce a calculated or derived result. The derived results if not being confirmed can be overridden manually.
- 10) In-built calculation management feature for building Calculations where user can select from standard functions, or create his own list of extended functions. Formulae as defined in current tests must be supported. These will be shared by THSTI at the time of requirements study.
- 11) Inter-Test Calculation Support for Configuration of equations for performing Inter-Test calculations, wherein Equations can fetch multiple operands from result values

of other tests from the same Sample or other Sample, and perform many operations, and many intrinsic mathematical functions.

- 12) Intra-Test Calculation Support for configuration of equations for performing Intra-Test calculations. Equations can fetch operands from many values within the same test and perform many operations, and many intrinsic mathematical functions.
- 13) Calculation equations based on basic as well as advanced math functions such as average, sum, regression, etc.
- 14) Validation of entered results against limits from the specification sheets for the given Test, whether entered manually, automatic or derived against.
- 15) High-lighting of Invalid or off spec results using different color and text (In-Spec, Out-Spec etc). Results that are on specification but beyond the normal average should also be highlighted to help identify Quality give-away.
- 16) Specifications may be defined on the basis of one or more of the following: test type, sample type/test type, sample type/test type/customer, sample type/test type/customer/product grade. All specifications are maintained as versioned records and bound to tests when logged or entered. In this way an intact historical record and the ability to re-process results according to the specification in effect at the time of testing is maintained. Alternatively, any sample/test may be rebound to newer specifications if desired.
- 17) Rules for number of decimal places, significant figures, rounding, truncation, scientific notation, etc, , settable individually for each component.
- 18) Capability to define limits in the specification as Minimum, Normal and
- 19) Maximum Limit. For E.g.: Off-spec < Near Prime < Prime > Near Prime> Off-spec
- 20) Validation of Alphabetic results against the ordered list of allowable values and the result value's position. For e.g. In the copper corrosion test, the test results are entered as 1A, 1B, etc. Textual dropdown results also to be subjected to Specification Check.
- 21) User configurable Order of the components of a sample in result entry screen.
- 22) Work assignment to Analysts: Provision to assign work for analysts Sample-wise, test-wise, role-wise, and instrument-wise, etc. as per business logic defined by THSTI at the time of requirements study.
- 23) Provision to configure work assignment as per roles. System should support definition of a Role according to a cluster of Tests to be carried out (One or more tests of a sample with one or more tests of another sample can be defined as a cluster). If a role is assigned to a particular analyst, whenever a new sample is logged, the relevant sample-test combinations are to be assigned automatically to that analyst till his role is changed in system. Suppose if the same role is assigned to more than one person, any of the assigned analysts should be able to enter result. Person who entered the result should be tracked by his login credentials. If a sample or test is not assigned to anybody, then any analyst should be able to enter result against any sample or tests.
- 24) View for Work assigned to analysts, completed and pending - Analyst wise, location/ source wise etc.

- 25) Specifications should have change history associated with them. Reports for earlier dates shall have the specifications applicable on the corresponding date.
- 26) Provision for multi-level specifications.
- 27) Triggering notification in the form of SMS / e-mail configured alert
- 28) Group result entry for samples of similar nature.
- 29) Provision to use 'alias' (short names) for the component names for making matrix form reports and other requirements. Both the component name and the alias should be used to reference the component.
- 30) Calculation equations based on user-defined functions
- 31) Provision to define a 'Range' for valid results and to restrict the entry of Result value beyond defined Range. E.g. System should not Accept a value for pH more than 14 as there is no pH > 14
- 32) Trend of results be displayed for past 5 samples while entering results (to be configured for a specific group of users)
- 33) Password prompts after entering all the results and before authorization.
- 34) Deletion (nullification) of a result entered by mistake against a component of a sample which was not done without giving any alternate value.
- 35) Each test should have cost associated with that and it should be possible to print the internal cost and the quote/ proforma invoice as chargeable cost to the client.
- 36) Provision for prioritizing tests/samples while assigning tests to analysts.
- 37) Special Samples: 100% of the test results are to be captured in LIMS. Hence, even if a new sample which is not configured in LIMS, comes for testing during odd hours, the sample name should be entered as free text and the test methods are to be assigned from the available list of test methods for result entry and the results should appear in the relevant reports. There should be provision to capture 'Reason for Testing', 'Source of sample', 'Sample brought by', 'Parameters needed', 'By when the results are Expected' etc when we log a special sample.
- 38) While approving result wise, only the entered results should appear for bulk approval, leaving empty field for result entry.
- 39) Provision to generate work-sheets of Samples assigned to Analysts.

1.4 Authorization and Publishing of Results

Mandatory functionalities

- 1) Authorization at Test Level as well As Sample Level.
- 2) Only confirmed results to be available to users.
- 3) Option for bulk approval of the results unit wise or sample wise.
- 4) Provision for auto-completion.

- 5) A cumulative view of all the results for a selected period for a particular sample type/ client to the approving person at the time of approval. Off spec results to be highlighted in a separate color.
- 6) Proper system controls to ensure no further processing of the results after the Authorization stage.
- 7) Remarks column in the format of a test result. This could be for on-spec or off-spec products.
- 8) A Remarks column for entering General Remark about the Sample.
- 9) Provision to re-activate an Authorized Sample for Result Entry, by Authorized users.
- 10) Automatic 'Sample completion' and 'Sample Authorization'.
- 11) Availability of results, on authorization, for creation of proforma invoice with the test rates.
- 12) Option to provide discount to the test rates for specific client/ project.
- 13) Option of pushing Numeric as well as text results.
- 14) It should be possible to create a price / test for each test and cost / test for each test.
- 15) Provision for Multiple levels of authorization. Finished products need two levels of approvals, where as unit / routine samples need one level of authorization.
- 16) It should be possible to create folders of Projects/ Sub Projects client wise and keep dashboard of status at project / experiment level.
- 17) It should be possible to have comments on the project level reports as Summary or the test report for samples submitted with summary page.

1.5 Security and Audit Trail

Mandatory functionalities

- 1) Provision to login in using the same user name and password as user uses for Windows domain authentication.
- 2) Provision to login using user name / password defined in LIMS solution.
- 3) Option for defining roles and access permissions.
- 4) Option for providing Role-based access to the menus, screens, functions and information should be available. The extent of access to information for any particular user/viewer shall be based on the level in the organization as decided by THSTI. The system should have in-built features to configure these levels as roles.
- 5) Feature of defining Session Timeouts if the system is not in use for a defined time period (say 15 minutes). This is to force users to re-enter their login details during a session if there is a period of inactivity which exceeds the specified limits.
- 6) Audit feature with logging. It is preferred to have 2 kinds of Audits
 - Silent Audits which happen in the background giving the user no indication that an audit transaction has been recorded.
 - Prompt Audits which display a pop up dialog box asking the user to state the reason for the action taken.

- 7) The Audit Module should record all significant changes to the LIMS database.
- 8) When an audit event is triggered, the audit module will record:
 - a. The change that was made (value before and after change)
 - b. The login through which change was done.
 - c. The time and date at which change was done
 - d. The reason that the user gave for making the change
- 9) Security features should enable administrator to control log in to the system at user level, IP Address level. He should also be able to define roles to control assignment of menu options and functions. Users can be assigned one or multiple roles as required.
- 10) Viewing facility for looking at data recorded by Audit module.
- 11) Option for introducing Electronic Signatures.
- 12) User to be prompted for electronic signature when they attempt to perform a system action, which has been configured to prompt for a signature for e.g. while authorizing a sample.

1.6 Reports and Search Facility

Mandatory functionalities

- 1) LIMS should have inbuilt reporting engine. Reporting option should be flexible. No programming knowledge should be required for getting the reports off the system.
- 2) LIMS Database structure / schema and knowledge about the same shall be shared by Vendor
- 3) Option to pre-define the presentation sequence of tests (be it on screen or in print) i.e. the order in which they should appear. The sequence may even be different for screen display and for printed reports.
- 4) Option to export the generated report to a range of file-formats such Excel, HTML, PDF, Text, etc.
- 5) Facility to run reports on a scheduled basis at specific times for e.g. at the end of the shift
- 6) Option for generating reports filtered by a parameter (location, sample type etc.) based on user requirement.
- 7) Vendor should provide COA format and 5 report formats as per our requirement. (total 6 reports)
- 8) A group of landing pages for Project Manager, Experiment level (group head) and user level be made available (Total 5 landing pages).
- 9) Configuration and development of the 6 reports shall be carried out by Vendor with active involvement of our core team members and vendor shall transfer the knowledge about database structure / schema, business logic, to our core team members.

- 10) Flexible formatting of Reports wherein user will be able to specify the layout of the information. The Report formats should be in-line with requirements of ISO/IEC 17025 Standard.
- 11) Provision to initiate e-mail/SMS pop up alerts with user-defined messages for pre-determined events and status.

1.7 Instrument Maintenance & Calibration, Training Records of Analysts

Mandatory functionalities

- 1) Instrument Calibration and Maintenance records should be stored in the system facilitating compliance to NABL/ ISO 17025 guidelines.
- 2) Availability of Instrument history details to keep track of calibration dates, store SOP's, Test Methods, maintenance activities, maintenance details etc. System should also be capable to issue calibration reminders, Maintenance Reminder etc.
- 3) Facility to maintain a regular service/calibration schedule for lab equipment.
- 4) The Calibration schedule should identify
 - a. Date of last service
 - b. Date of last calibration
 - c. Period between services
 - d. Period between calibrations
 - e. Date of next service
 - f. Date of next calibration
 - g. Results of last calibration
 - h. Notes on last service
- 5) It should be possible to define Calibration schedule, register the servicing person details, log in calibration samples and verify the results to ensure that instrument is under calibration.
- 6) It should be possible to define regular service schedule, register the service provider details.
- 7) Retention of historical data relating to individual services and calibration. It should be capable of producing historical reports on services and calibrations (including dates, technician who carried it out and cause of service/calibration). It should be capable of producing control charts trend analysis of calibration (scheduled and unscheduled) results
- 8) Besides maintenance and calibration of laboratory instruments, some instruments require regular validation checks using standard reference material. The LIMS Solution should provide facility to:
 - a. Generate worksheets for validation checks according to validation schedules,
 - b. Highlight those beyond Warning Limit or Control Limit when validation
 - c. result entered
 - d. Capture and display date/time and analyst against each result,

- e. Generate control charts for viewing (selection by instrument tag number),
 - f. Generate control chart reports monthly and on demand
- 9) Feature to stop a sample being allotted to an instrument that has been taken out for calibration/ services. Option to Lab Manager to override the alert with proper reason under electronic signatures.
- 10) Training details of LIMS users should be captured for record and authorization purpose.
- 11) The training records to be linked to the instruments to trace the training required to carryout the tests on the instruments.
- 12) As per ISO 17025/ NABL requirements, it should be possible to register the training records of the LIMS users with various levels of expertise and link with the tests. System should alert when user with invalid training credential is allotted the samples/ test.
- 13) Display authorization of analyst to operate equipment and to perform a test based on training
- 14) Facility to adapt to all type of analytical instruments for possible LIMS interface.

1.8 Inventory Management for Reagents, Consumables and Spares

Mandatory functionalities

- 1) Features to manage stock of reagents, glassware, consumables, kits (ELISA,PCR) and spares that are used and maintained by the laboratory.
- 2) Option for maintaining the item master as well as the item planning data required for replenishment such as the re-order level, Minimum order quantity, Safety stock etc. THSTI team would ensure the static data of these items are populated in the system.
- 3) Option for maintaining the items at user defined locations in order to determine the overall inventory of the item in the laboratory Capability to issue material from one location to another through authorized users.
- 4) Option to keep track of inventory of chemicals consumed in laboratory from the stores attached to the laboratory (including the glass ware). Low inventory alarms should be configured.
- 5) Retain sample Management should be provided with provision to location management, tracking samples in specific locations, pull out schedule alert for samples to be tested and kept back in locations. Tracking of results of pulled out samples.
- 6) Sample destruction should be alerted after specific time period.

1.9 Regulatory Compliance

Mandatory functionalities

- 1) Support regulatory requirements of the Laboratory including Audit trails, Time and Date stamping of all actions and Version control of all Reference data.
- 2) Provide convenient on-line access to earlier versions of Reference data.
- 3) Capability for Evaluation of measurement of Uncertainty as per ISO/IEC 17025 Standard.

1.10 Location Management

- 1) System should have extensive hierarchical location management configuration in the core function. Each level of location should have parent and child locations to be linked.
- 2) Samples, Standards, instruments and other desired entities should be linked to the location when required. Dashboards should have linking option to the locations for display of data based on location
- 3) Chain of Custody: Samples, standards, stocks, inventory movement from location to location should be tracked with date, time stamping and reasons where required.
- 4) THSTI would have Deep Freezers, Refrigerators, cup boards and lab spaces as locations and samples/ inventory movement among these should be tracked as well as person to person transfer of custody.
- 5) Location wise report , if needed should be possible to generate adhoc from the explorer itself.

1.11 Lab Execution System/ ELN

- 1) It should be possible to carry out the sample preparation, standard preparation, working standard preparation, column management, buffer preparation, routine calibration, monthly, yearly calibration of instruments through electronic SOP system captured in LIMS. NO paper work should be required for Lab Notebook activities.
- 2) It should be possible to interface instruments directly to the ELN/ LES system and authorization plan should be enabled where required. Complete audit trail should be captured.
- 3) The ELN/ LES system should be by the same OEM and be seamlessly integrated to the LIMS system. It should not require separate Master build up, server requirements. It should be possible to carry out the executions from PC, Laptop and tablet (Mobility) as required by us.

2. TECHNICAL:

2.1 Bidder's Scope of Supply

- 1) Bidder to offer suitable, easy to implement, cost effective, reliable and scalable LIMS solution. Bidder will address each item as defined in the Functional and Technical specifications of this document.
- 2) Bidder shall do a Proof of Concept (POC) of his solution covering key functionalities and features. This will be considered as an essential qualification for meeting our technical requirements. 2 working days will be allotted for the POC and bidder would be asked to give the POC The following should necessarily be shown as part of the demo
 - a) Logging in of Scheduled and Un-scheduled Samples
 - b) Receipt of Samples using Bar-code reader
 - c) Display / Alerts of Samples logged in but not received
 - d) Result entry
 - e) Validating of Results against Specifications
 - f) Authorization of Results
 - g) Search facility for Samples as per user requirement
 - h) Certificate of Quality generation covering parameters as per format provided
 - i) Integration with at least one balance (to be brought by vendor) and example result file capture
 - j) Integration capability with regular used lab Instruments like GC, HPLC, ICP.
 - k) System audit trail encompassing exhaustive user activities
 - l) Super admin control
 - m) User Dashboard
 - n) Functionality with the mobile app.
 - o) Proof of live system running as per the claims made in the documents.
- 3) Bidder to submit proposal which includes following for realization of complete assignment
 - a) Supply of Software and Licenses to THSTI
 - b) Supply of Services.
 - c) These will be classified into following heads:
 - I. Requirement Study for LIMS Implementation at THSTI and submission of FDS (Functional design specification) , Data Migration Plan for legacy system (only master data) and Technical Design Document submission followed by sign-off
 - II. Implementation Services THSTI
 1. Installation of software
 2. Configuration / Customization as per FDS
 3. Integration with LES (by the same OEM)

4. Deployment
5. User Acceptance testing
6. User, administrator and Report writing training
7. Roll-out and Sign-Off
8. Post Roll-out Support: Warranty
9. Documentation and Deliverables
10. Annual Maintenance Services
11. Instrumentation Integration Services

2.2 Supply of Software and Licenses

1) Supply of Software

- a) Bidder shall enlist all the software to be supplied by him for implementing the LIMS solution at THSTI. This will include Core LIMS software, Interfaces to LES/ELN/SDMS, Instrument Interface, connectors, adaptors, 3rd Party components and other tools, if any. Bidder shall indicate against each of the software component, its release date, version, hardware / software pre-requisites, whether it is Bidder's own software, third-party or open-source software. Bidder shall submit this list at the time of technical bid submission.
- b) Bidder shall supply the latest version of all software mentioned in the list above, on Media.
- c) Bidder shall supply License for enterprise-wide usage. THSTI list of instruments include ELISA readers, RTPCR, CE. LIMS vendor to specify their requirement for instrument interface.
- d) Any physical connectors needed like RS 232 Cable, should be informed to us in advance. It would be given by us for the vendor to make the connection and demonstrate successfully.
- e) Patches, Service packs, new version of the LIMS system shall be made available in future.
- f) Bidder shall offer the system which is inclusive of database with required access license. For e.g. Oracle, SQL Server, etc. THSTI should not have to purchase separate license for the same.
- g) All components, modules, software, applications, Interfaces etc. which are likely to be covered / associated / integrated under the software shall be supplied for usage without any restrictions or additional cost.
- h) Vendor shall clearly state the software which will not be provided by them and which is essential for LIMS implementation. This shall be stated at the time of technical bid submission.

- i) Any software which is not explicitly mentioned by vendor at the time of technical bid submission shall not be supplied and the cost for the same shall be borne by the vendor.
- j) Instrument Interface should be of latest technology with its own database. It is highly preferred that the LIMS bidder offer their own Instrument Interface module rather than third party products, for better support. It should be robust enough to handle multiple instruments with conversion of data to vendor neutral file formats like XML. Bidder should submit proof of having implemented such system with their LIMS in any subject sample testing laboratory connecting Lab instruments to LIMS. It should be possible to collect instrument data and PDF of reports and the interface read from the PDF of the report from instruments for parsing and mapping.

2) Supply of Licenses

- a) Vendor to clearly state if the prices are software based with unlimited licenses or license based with no software fee.
- b) If the licenses are chargeable, specify if it is concurrent user license model or named user model. We prefer concurrent user license model.
- c) All above licenses, User license, instrument license etc. shall be perpetual in nature.
- d) Any software which is not explicitly mentioned by vendor in the technical bid shall not be supplied by THSTI and the cost for the same shall be borne by the vendor.
- e) Bidder should provide Enterprise-wide License Agreement copy.
- f) LIMS license supplied shall have comprehensive usage in environments production, validation and development servers in THSTI.
- g) License should be applicable for Virtual environments.
- h) The functioning of License mechanism should not require any hardware dongle.

3) Supply of Services

Requirement Study for LIMS Implementation at THSTI and submission of FDS, Data Migration Plan and Technical Design Document submission followed by sign-off.

- a) The Requirements Study shall be started by the bidder within 15 days of award of contract.
- b) The purpose of the requirements study is for the Bidder to understand the exact scope of the project both from functional as well as technical aspects and document the same as the basis for implementation.
- c) To carry out the requirements study, Bidder shall be required to visit the requisite departments at their own cost.

- d) Single point contacts shall be provided from the respective departments for ease of co-ordination. These will constitute the core LIMS Implementation team. Similarly, Bidder shall also designate the Project Co-ordinator who will be the single point of contact for THSTI.
- e) Bidder shall study for each point in the functional scope
 - I. The AS-IS business process being followed
 - II. The existing LIMS functionality that addresses the point (If applicable)
 - III. User's Requirement from the new system
 - IV. If the point is related to a reporting need, then report template and purpose will be studied. 10 Reports to be taken up for development in the first phase will be identified during this study
 - V. If the point is related to Integration, then the data interchange and related event triggers will be studied. Requirement for integration with LIMS will also be defined at this stage.
 - VI. Bidder shall Identify and finalize the list of Laboratory Instruments from each site, not exceeding 07 nos., that will be taken up for Integration in the Instrument Integration phase of the Project. This will include the Type, Make, Model of the Instrument.
 - VII. Bidder shall also study the technical scope and the overall IT framework, standards and Integration between LIMS and other systems
 - VIII. After completing the interactions at THSTI Bidder will summarize the same and prepare a Minutes of Meeting for each site and send it to the core LIMS Implementation team.
 - IX. Bidder shall cover following in the agenda of the workshop
 - 1. Product Familiarization training
 - 2. Presentation and discussion on Functional scope which is common across the
 - 3. Specifications for hardware and networking requirements if any, like Barcode Printers, Barcode Readers, Electronic Laboratory Notebooks (ELNs), additional computers, adaptors, networking equipment, etc.
 - X. The bidder shall make use of this workshop to finalize the functional design specifications, data migration plan and technical design document.
 - XI. Following the requirements study and the workshop, Bidder shall prepare and submit the FDS (Functional design specification), data Migration Plan and Technical Design Documents.
 - XII. Though the Requirements study will be done for all sites together, the LIMS implementation and Go-Live will happen independently.
 - XIII. FDS document shall cover the logical system flow, data organization, system inputs and outputs, processing rules, and operational characteristics of the product from the user's point of view. This shall be

done using any standard approach such as Prototyping, Use-Case Modeling, etc.

- XIV. FDS document will enlist the customization that will be done in the solution.
- XV. FDS document will enlist all Reports required by users, and indicate clearly
 - 1. Which 10 reports are in the scope of implementation by the bidder
 - 2. Which reports are not in the scope of Implementation by the bidder
 - 3. Strategy for developing reports falling under (1) and (2)
- XVI. FDS document shall contain specifications for hardware and networking requirements if any, like Barcode Printers, Barcode Readers, Electronic Laboratory Notebooks (ELNs), additional computers, adaptors, networking equipment, etc.
- XVII. FDS document shall be the final blue print which shall cover all requirements captured and elaborated during the requirements study phase and shall be the scope for implementation services.
- XVIII. Technical Design Document shall cover the proposed Information Technology Architecture for Enterprise-wide LIMS including
 - 1. Data Server locations for Production as well as Disaster Recovery
 - 2. Application and Database instance architecture (Option for Centralized hosting of Application and Database and distributed hosting to be provided. THSTI will decide which one to go in for)
 - 3. Connectivity architecture
 - 4. Network bandwidth requirements for smooth functioning architecture
 - 5. Redundancy system
 - 6. Backup and Recovery system
 - 7. Hardware / Software pre-requisites
- XIX. The Information Technology Architecture for Enterprise-wide LIMS proposed in Technical Design document must be in line with the IT Framework, Standards and Policies implemented
- XX. Data Migration plan Document shall contain the detailed plan for migration of legacy data (Masters as defined) from existing LIMS solutions to the proposed LIMS solution. It shall enlist clearly the activities involved in Data migration, responsibilities and Bidder in ensuring that data is correctly migrated from legacy system to the new one.
- XXI. Bidder shall submit the FDS (Functional design specification), and Technical Design Document for validation and 'Approval SIGN-OFF' by LIMS Core implementation team
- XXII. Following the 'Approval SIGN-OFF' of FDS, Data Migration Plan and Technical Design Document, supply of software and licenses and hardware procurement by THSTI, bidder shall carry out installation, configuration, customization, data migration, testing, report

development, training, implementation, and rollout phase-wise and spelled out in the implementation services section.

XXIII. The FDS, Migration Plan and technical Design document will have a Go-live 'SIGN-OFF' Section,

XXIV. The requirements study will be deemed complete only on submission of the deliverables and 'Approval SIGN-OFF'

2.3 Implementation Services

- 1) After the requirements study phase, Bidder to submit a detailed project plan, specifying the timelines, resource loading, roadmap and major milestones for the implementation. The same will be reviewed and evaluated by THSTI and has to be approved by THSTI. The project plan will then be jointly approved by THSTI and Bidder.
- 2) Bidder shall provide turnkey Implementation services in phases
- 3) Bidder shall provide team structure from Bidder's side. THSTI will have an appropriate team in place for implementation.
- 4) In case, we want to avail additional services, which are not covered in the present scope of services, Bidder shall agree to do so at services rates quoted in the commercial bid. These rates should be exclusive of costs towards travel, lodging and boarding of Bidder's consultants.

2.4 Post Roll-out support: Warranty

- 1) Bidder shall warrant that the LIMS solution deployed will fully satisfy the functional requirements as per the scope of work and shall have no defects arising from design or workmanship or any act or omission by them.
- 2) Warranty period shall be for 3 year from date of issuance of the Final Acceptance Certificate.
- 3) Vendor shall provide and apply the LIMS software patches, upgrades etc. during the warranty period.
- 4) Vendor shall revise the documents whenever changes are made in the software during the warranty in the form of addendum to original documents.
- 5) Vendor shall also provide/apply the patches, upgrade etc. for the 3rd Vendor components, tools, adaptors, connectors etc. and certification wherever necessary, during the warranty period.
- 6) Vendor shall support and troubleshoot issues without affecting the production system.
- 7) Vendor shall provide support through on site visit, telephone, e-mail, support web site, web-ex, voice mail etc, depending on the criticality of the issue.
- 8) During the warranty, Vendor shall agree to provide the patches, fixes, upgrades, new release etc. without any additional cost.

- 9) All error messages in the system shall be descriptive clearly indicating the nature of error and action expected from user.
- 10) During warranty period, Vendor should carry out Audit of the implemented solution once in a year, for gap identification and submit a report to that effect.
- 11) Vendor should submit a quarterly report of maintenance carried out on the system during the warranty period.
 - a) Vendor should carry out workshops once in a year to showcase product roadmap and new features / capabilities.
 - b) Vendor a/c manager for THSTI should make a site visit every 6 months during the warranty period.
 - c) Any change in the name of the company should be informed by the vendor to THSTI and steps should be initiated to ensure that the name change formalities as per legal requirements are met.

2.5 Documentation and Deliverables

- 1) Vendor shall prepare and submit following documents for the project in PDF and Word format
 - a) Functional Design Specifications (FDS) document
 - b) Technical Design document
 - c) Data migration plan
 - d) Test criteria for site acceptance, testing procedure and integration testing procedure
 - e) End-user manual
 - f) Operational manual for administrators
 - g) Report writing Manual
 - h) Project Plan and other Project Documentation
- 2) Template for all the documents mentioned in points a) to h) shall be approved by THSTI.
- 3) Vendor shall maintain proper versioning of all documents prepared and listed under point a) to h) till the end of warranty period.
- 4) One set of manuals in electronic format to be made available to each site.
- 5) Bidder shall Supply Solution Software on with Media for Server, Client and Interfaces, etc.

LIMS should be configurable easily by the IS team of THSTI. We prefer to have reduced training requirements and familiarization of languages and technologies used by the LIMS vendors. For this, a generic, GUI based workflow engine is to be offered by the LIMS vendors.

2.6 IT Specifications

- 1) LIMS system shall support VM ware/Virtual environment. There should be no CPU or core restrictions for hosting on VM Ware / Virtual environment.
- 2) The LIMS system shall have a well-defined strategy for Archival / Retrieval of data.
- 3) Knowledge transfer for both Application maintenance and Report development shall be ensured by the vendor.
- 4) System speed is prime requirement. Transaction response time shall be acceptable to THSTI.
- 5) The Reporting facility provided by the System should not require any separate client installation. No specific software component shall be required to be installed on individual clients for printing / viewing of reports through web interface. The Reporting software should seamlessly integrate with Microsoft Office Application.
- 6) The Client Application should co-exist with the other Client software implemented
- 7) The proposed solution should also support Document Management addressing the Creation, collection and management of documents in an electronic environment.
- 8) Solution should be easily configurable to suit the dynamic needs of the Laboratory, without the need to write customized code.
- 9) The configuration tools should be easy to use and allow for change of Menus, Screen design as per user requirement.
- 10) Solution should have flexibility to define a separate LIMS database for future addition of other laboratories of different workflows.
- 11) Should have logically separate Database groups for Current and Archive data, enabling user to switch easily from Current mode to Archive mode from the same client application.
- 12) Solution offered by Bidder shall be browser-based.
- 13) Solution shall support common browsers with default as Microsoft IE.
- 14) Solution shall also have a client-based version which we may choose to implement at selective locations.
- 15) Solution offered must be user-friendly, intuitive with in-built help / support facilities.
- 16) Solution for Integration to Laboratory instruments must not be a third-party solution.
- 17) System should support and Integrated with LDAP (Lightweight Directory Access Protocol), Single Sign On for all applications.
- 18) Automatic closure of session/log off, if the system is idle for more than 15 minutes. Duration shall be configurable.

2.7 Functional Requirements

LIMS Application Development and Hosting at THSTI premise should address following functional requirements:-

- 1) The LIMS application functions should be user friendly.
- 2) The solution should be customized to capture all information required by all the stakeholders.
- 3) The solution should provide for Addition, Edit and Update for all Records as well as user privileges for the administrator.
- 4) The solution will be able to conduct Validation, Editing, Storing, Profiling, Reporting etc. from the database.
- 5) The solution should be able to guard against malicious user input, SQL Injection, session fixation and unauthorized database access.
- 6) The System should have robust authenticated role based architecture that can be configured as per user requirement.
- 7) Expansion of the solution should be easily maintainable through plug-ins with authorization of physical and logical movement of electronic information.
- 8) The system should provide monitoring tools with Dashboard facility for higher level supervision at client end.
- 9) The solution should provide for SMS and Email Notifications as required by end client to each of the stakeholders at various predetermined stages.
- 10) The solution should provide for creating MIS reports for the various stake holders.
- 11) The solutions should have capability for enabling authenticated User Access for approved Users based on Admin Rights and privileges.
- 12) The solution should be designed to ensure confidentiality and security of all Data all through the process.
- 13) The solution should have Online Documentation, On-line help, Field-level help, Screen-level help etc.
- 14) The solution should have single sign-on access across applications and should be intuitive, with easy-to-use user interface that can be accessed via the web interface.
- 15) The solution should provide performance statistics for the CPU/ Memory, database, Application servers.
- 16) The solution should have ability to:

- a) Support configurable Password policies
 - b) Support TCP/IP, HTTPS, HTTP
 - c) Provide automatic time out for entry transaction
 - d) Configure the number of permissible application log-in attempts
 - e) Support role based access control
- 17) The solution should be web enabled with role based access control for all the internal and external and stakeholders to use it from intranet and internet. Users and administrators should be able to access the system with any leading web browsers like Internet Explorer, Firefox, and Chrome etc.
- 18) The solution should come with inbuilt tools for data migration, upgrades etc.
- 19) The system will display the list of users and allow each user to be assigned roles, privileges as well as alter or revoke them.
- 20) The system will allow the system administrator to reset passwords, in which case the user will be automatically notified using email of this fact and the user will be asked to log in to the system within a specified period after which a new password request will need to be made by the user.
- 21) The system will allow the system administrator to maintain a list of privileges and assign, alter or revoke rights that may be view, add/create, edit/alter/update, delete/remove/archive to each form control of every user interface.
- 22) The system should provide facility so that; Passwords will be changed every 90 days (or other period). The systems will enforce password change with an automatic expiration and prevent repeated or reused passwords. The system administrator shall have the power to set exceptions for this.
- 23) The system should provide facility so that; On allocation for the first time as well as reset of password by the system administrator for lost passwords, the user will be forced to change the password
- 24) The system should provide facility so that; Passwords must be stored in encrypted forms by the system and these cannot be retrieved by the system administrator who may only reset the password.
- 25) The Solution should provide integrated document management system.
- 26) Document management system should be able to store documents related to transactions and should allow viewing document without requiring any external tool.
- 27) Integration Capabilities
- Hardware/Equipment Integration
 - Integration with barcode generator

2.8 Security Principles

- 1) The system must follow a role based access control at all levels.
- 2) The system must support extensive logging at all levels and associated tools for audit and quick alerting in case of unforeseen malicious access.
- 3) All data on the LIMS software must be secured and there should be no direct access to it other than through well-designed, secure & well-established protocols.
- 4) Data privacy will be given appropriate emphasis with commensurate liability and indemnity provisions. All the hardware assets must also be secured throughout their life cycle as they may contain sensitive data.

2.9 Application Security Principles

- 1) **Establish secure defaults:** By default, the applications should be secured, and it should be up to the user to reduce their security – if they are allowed. All the passwords or login details or financial transaction related information shall not be transferred to or from the server in plain text. SSL 128 bit encryption method can be adopted to secure such details.
- 2) **Security and Access Management Layer:** Access management and security are the critical components of the solution architecture. Single Sign-On (SSO) and Role based access are achieved through the identity assertion, credential management and directory services components.
- 3) All types of network attacks which were made possible due to any reported vulnerability found in the software/technology used by the bidder must be identified and counter measures must be put in place without any additional cost i.e. free of charge. If required, any update or changes made in the source code of the product shall also be provided without any additional cost i.e. free of charge. Such Changes & Updates should be covered under the warranty clause.
- 4) All data should reside within a specific THSTI infrastructure developed for the purpose.

2.10 Management Principles

- 1) The management of system shall be SLA (Service Level Agreement) based.
- 2) System Management shall follow all processes as per to Information Technology Infrastructure Library (ITIL) standards. This includes Asset Management, Vendor Management, Configuration Management, Incident Management, Performance Management and Capacity Management.

- 3) Change Management should be automated to the maximum possible extent.
- 4) Real-time status of the system performance should be available at all times to system administrator desk.
- 5) System Management should intelligently perform root-cause analysis to rapidly bring the system back to normal working conditions.
- 6) It should be possible to proactively manage all the system hardware and software components maintenance and licenses throughout their life cycle.

All the requisite licenses for entire components needed for LIMS deployment and maintenance would be provided by the vendor.

3. DETAILED PROJECT PLAN:

| S.N. | Activity Description | Deliverables | Timelines |
|------|---|--|----------------------------|
| 1 | Visit to THSTI's designated lab. 1) The purpose of the visit is to understand as-is process flow in the laboratories and make necessary alignment of the project execution plan submitted by the successful bidder in its bid. 2) THSTI shall facilitate successful bidder's visit and shall also depute its representative to accompany the successful bidder. | Visit Report and key observations for the purpose of implementing LIMS | Project Start Date+ 5 days |
| 2 | Inception meeting: 1) To discuss and update the project execution plan 2) Finalize timelines for key stages of LIMS implementation 3) Discuss and agree on roles of different stakeholders and task assignment 4) Identify any issues likely to affect project progress and discuss, how they could be resolved 5) Discuss and agree the processes for resolution of issues during execution of the project 6) Finalize administrative arrangements for the project | Inception Report | Project Start Date+10 days |
| 3 | System Requirement Study: 1) The successful bidder is required to carry out an assessment of the current processes, systems, operation, information exchange requirement, process flow by visiting concerned lab at THSTI and holding discussions with key Laboratory in-charge and other staff. 2) The successful bidder shall conduct as-is business process study by: a) understanding detailed business process. b) Identifying key issues and challenges in the current environment, assessing current forms and formats being used. c) Analyzing the information exchange and reporting requirements (external and internal) d) Listing out positions and their roles and responsibilities. e) Listing out equipment, lab consumables required for day-to-day | System Requirement Study (SRS) Report | Project Start Date+30 days |

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| | <p>functioning of lab.</p> <p>3) The successful bidder shall prepare System Requirement Study Report and submit the same to THSTI for validation and approval.</p> | | |
| 4 | <p>System Design Document</p> <p>Based on the as-is business processes and System Requirement Study, the successful bidder on behalf of successful bidder shall be required to carry out the following:</p> <p>a) Prepare a task-level to-be business process document which shall describe how existing processes will be executed through LIMS implementation</p> <p>b) Finalize functional and technical requirement specification based on to-be business process design.</p> <p>c) Prepare System Design Document (SDD) defining the system architecture, modules, database design, interfaces, data requirements and reporting requirements in line with finalized requirement specifications</p> <p>The successful bidder shall obtain approval from THSTI before proceeding with the Design, Development based on SDD.</p> | System Design Document (SDD) | Project Start Date+40 days |
| 5 | <p>LIMS Design and Development:</p> <p>1) Based on approved SDD, the successful bidder shall carryout the following functions:</p> <p>a) Perform the development of proposed LIMS modules based on approved SDD</p> <p>b) A standard methodology shall be adopted for LIMS development covering entire Software Development Life Cycle (SDLC)</p> <p>c) The project manager or the person appointed by the bidder for this purpose, shall demonstrate the LIMS Modules to THSTI during various stages to take feedback from THSTI.</p> <p>d) The LIMS Modules shall be tested by the users at THSTI during various stages of completion.</p> <p>e) The feedback provided by THSTI users after each round of testing should be documented, demonstrating that such feedbacks have been duly incorporated</p> | Module-wise report on development of LIMS and Ready to Test LIMS software | Project Start Date+120 days |

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| 6 | <p>LIMS Testing:</p> <ol style="list-style-type: none"> 1) The successful bidder shall design the LIMS software testing strategy including test script, traceability matrix, detailed test cases and conduct testing of various components of LIMS. 2) The successful bidder shall use appropriate tools for various types of testing to enable THSTI to check the software on various parameters like performance, security, stability etc. 3) The results of testing process should ensure that the objectives, scope of work, functional requirements are met successfully. 4) The successful bidder shall obtain the sign-off from THSTI on testing approach and plan. 5) The successful bidder shall perform the testing of the LIMS based on approved test plan, documenting the results and shall fix the bugs found during testing. 6) The successful bidder shall provide all support to THSTI or its representative/agency to conduct acceptance testing which will be performed on the server provided by THSTI. 7) The successful bidder shall set up the software along with other components, libraries, dependency software, etc., on the physical/virtual machine provided by THSTI. THSTI shall only provide the hardware platform and all the other necessary software including the Operating System, Database software, other paid software shall be provided by the successful bidder at their own cost. 8) In case THSTI observes some deficiencies in the LIMS solution while doing testing, a discrepancy communication shall be issued to the successful bidder citing deficiencies observed and timelines within which these deficiencies shall be removed. | <p>Testing Approach and Plan.</p> <p>All the software licenses, keys, administrative passwords of the system/database etc.</p> | <p>Within 30 days of delivering the complete module as per 5 above</p> |
| 7 | <p>Data Digitization and Migration</p> <ol style="list-style-type: none"> 1) The successful bidder shall conduct data digitization and migration study and shall prepare the data migration strategy and plan for migration of existing digital and hardcopy data and documents to LIMS. 2) The successful bidder shall identify the data elements (both manual and digital records) to be uploaded in LIMS database based on business requirements 3) Prepare template for data collection from manual records and share with the users. 4) Prepare master data format and schematics 5) Provide training to users in data collection and verification of manual records 6) Guide users in data digitation and data cleaning of manual records before uploading the same in LIMS database 7) The successful bidder shall optimize all the existing forms, reports and registers before migrating the same into LIMS 8) Migrating data from any IT-based system/tools to LIMS database and uploading the digitized data (digitized from manual register by | <p>Report on completion of data digitation and migration to LIMS</p> | <p>Within three weeks of final testing and handing over of LIMS to THSTI</p> |

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|----|---|--|--|
| | <p>Labs) will be the responsibility of the successful bidder.</p> <p>9) Manpower support from THSTI will be provided for digitization of manual records.</p> | | |
| 8 | <p>Hands on Training:</p> <p>1) The successful bidder shall be required to train-the- trainer as designated by THSTI to enable them to effectively operate and perform the services using LIMS and become resource for conducting further training to users at THSTI.</p> <p>2) Train the staff, officers and people engaged with the designated THSTI lab.</p> <p>3) The travel cost incurred on this activity is to be borne by the successful bidder.</p> <p>4) The successful bidder shall prepare the training manual and end-user manual covering 'How-to-use' concepts of all the LIMS Modules.</p> | <p>Training Manual and end-user manual and Training completion report</p> | <p>Within three weeks of final testing and handing over of LIMS to THSTI</p> |
| 9 | <p>Go Live</p> <p>1) The system will be deemed qualified for GoLive when all the previous steps are completed and agreed by THSTI. The successful bidder shall grant a non-exclusive, non-transferable, non-assignable license to THSTI for using any of the bidder's or its licensors' proprietary material embedded in the LIMS Solution solely for the internal business purposes of THSTI.</p> | <p>Handing over/delivery document which comprises of necessary passwords, keys and the other deliverables as mentioned in the previous stages of the deployment. Go Live date will become the date of start for 3 Months deputation of 1 technical staff at THSTI's premises for the purpose of hand holding of the users during the initial phases.</p> | <p>Within one week of completion of training</p> |
| 10 | <p>Change Management:</p> <p>1) THSTI recognizes that implementation of LIMS shall bring changes to the processes and systems currently being used in Labs. The successful bidder shall be required to provide change management support in addressing the concerns of various stakeholders to ensure successful adoption of the LIMS by all the Lab officials. The successful bidder shall be required to:</p> <p>1) Assess the impact of LIMS implementation on the processes, organizational structures and systems</p> <p>2) Develop a comprehensive change management strategy for</p> | <p>Change Management Strategy and Plan</p> | <p>Within three weeks of going live</p> |

| | | | |
|----|---|--|---|
| | <p>addressing the concerns of lab officials to minimize the impact of changes to enable adoption of the LIMS</p> <p>3) Identify key change agents who will assist successful bidder in conducting change management activities in labs</p> <p>4) Conduct consultations with all categories of Lab officials to identify their concerns and prepare suitable change management plan to address these concerns</p> <p>5) Include change management plan in the training of trainers and other staff.</p> | | |
| 11 | <p>Final Acceptance Certificate (FAC)</p> <p>1) THSTI shall issue the FAC to the successful bidder only on ensuring that the LIMS solution is fully functional as per the project scope for straight 30 days since Go Live.</p> | THSTI will provide the Final Acceptance certificate mentioning the date of issuance. | Within five weeks of going live |
| 12 | <p>Warranty Maintenance support to LIMS for 3 years</p> <p>1) The successful bidder shall provide maintenance support to LIMS for the period of 3 years from the date of issuance of Final Acceptance Certificate for LIMS by the Institute.</p> <p>2) The successful bidder shall provide help-desk support during maintenance period on all working days during normal office hours (9 AM to 5.30 PM) from an office in India.</p> <p>3) The changes necessary for smooth functioning of LIMS including enhancement of features and new requirements shall be incorporated and updated version of LIMS shall be provided to THSTI during the warranty period</p> <p>4) The successful bidder shall ensure that the devices, software's, modules, including all the items mentioned in the Handing over/delivery document by the successful bidder, shall have comprehensive onsite warranty/support during the Warranty period. For the Third Party software and their updates, operating systems, databases etc., the support should be ensured by the successful bidder.</p> | | Three years from issuance of Final Acceptance Certificate for LIMS by the Institute |

PART – C

(Price Bid Format and PBG format)

Selection of Agency for designing, developing, configuring, implementing, integrating, commissioning of Laboratory Information Management System (LIMS) software at THSTI, NCR- Biotech Science Cluster, Faridabad

Price Schedule 'A'

***Note: The Complete project cost should include 3 years comprehensive warranty, maintenance and support for each component and the project as a whole. The solution should be able to cater at least 5 concurrent users and its license cost for 3 years. All the costs including any dependency software, licenses, operating system, and travel expenses during the warranty period etc. are to be borne by the bidder.**

| S.no. | Product Details | | | Qty | Rate in Foreign currency | Rate in INR | GST% or any other taxes as applicable | Amount (Rs.) |
|-------|--|---------|------------|-----|--------------------------|-------------|---------------------------------------|--------------|
| | Name of module or software | Version | Make/Brand | | | | | |
| 1 | | | | | | | | |
| 2 | | | | | | | | |
| 3 | | | | | | | | |
| 4 | | | | | | | | |
| 5 | | | | | | | | |
| 6 | | | | | | | | |
| | Total cost inclusive of GST and other applicable taxes | | | | | | | |
| | Total cost in words | | | | | | | |

Note: The price quoted in foreign currency in shall be converted in Rupees at the selling rate of exchange applicable on the date of tender opening. The financial bid evaluation will only be based on the total cost as per the Price Schedule 'A' only.

Price Schedule 'B'

| S.no. | Comprehensive warranty, maintenance and support for each component and project as a whole | Rate in foreign currency, if any. | Rate in INR | GST% or any other taxes as applicable | Total cost for the year |
|-------|---|-----------------------------------|-------------|---------------------------------------|-------------------------|
| 1 | Fourth year since implementation | | | | |
| 2 | Fifth year Since Implementation | | | | |

PROFORMA FOR PERFORMANCE BANK GUARANTEE

(On a stamp paper of appropriate value from any Nationalized Bank or Scheduled Bank)

BG No.:..... Date.....

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| From The Name of the Bank | To Translational Health Science Technology Institute (THSTI), 3rd Mile Stone, Faridabad- Gurgaon Expressway, Faridabad – 121001 Phone: +91-129-2876 (check the contact number) |
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In consideration of the Translational Health Science and Technology Institute, Faridabad (hereinafter called "The INSTITUTE") having offered to accept the terms and conditions of the proposed

agreement between The Institute.....and..... (hereinafter called "the

Contractor(s)"for the work..... (hereinafter called "the said agreement") having agreed to

production of an irrevocable Bank guarantee for Rs..... (Rupees.....only) as a

security/guarantee form the contractor(s) for compliance of his obligations in accordance with the terms and conditions in the said agreement.

1. We (hereinafter referred to as the "Bank") hereby undertake to

(Indicate the name of the Bank) Pay to the Institute an amount not exceeding Rs..... (Rupees..... only) on demand.

2. We...(indicate the name of the Bank) Do hereby undertake to pay the amounts due and payable under this Guarantee without any demur, merely on a demand from the Institute stating that the amount claimed is required to meet the recoveries due or likely to be due from the said contractor(s). Any such demand made on the Bank shall be conclusive as regards the amount due and payable by the Bank under this Guarantee. However, our liability under this Guarantee shall be restricted to an amount not exceeding Rs..... (Rupees.....only).
3. We, The said Bank, further undertake to pay to the Institute any money so demanded notwithstanding any disputes raised by the contractor(s) in any suit or proceeding pending before any Court or Tribunal relating thereto, our liability under this present being absolute and unequivocal. The payment so made by us under this bond shall be a valid discharge of our liability for payment thereunder, and the contractor(s) shall have no claim against us for making such payment.
4. We (indicate the name of the Bank) further agree that the Guarantee herein contained shall remain in full force and effect during the period that would be taken for the performance of the said agreement, and it shall continue to be enforceable till all the dues of the Institute under or by virtue of the said agreement have been fully paid, and its claims satisfied or discharged, as per the terms and conditions of the said agreement have been fully and properly carried out by the said contractor(s), and accordingly discharges this guarantee.
5. We.....(Name of the bank)..... further agree with the Institute that the Institute shall have the fullest liberty without our consent, and without effecting in any manner our obligations hereunder, to vary any of the terms and conditions of the said agreement or to extend time of performance by the said contractor(s) from time to time or to postpone for any time or from time to time any of the powers exercisable by the Institute against the said contractor(s), and to forbear or enforce any of the terms and conditions relating to the said agreement, and we shall not be relieved from our liability by reason of any such variation or extension being granted to the said not be relieved from our liability by reason of any such variation or extension being granted to the said contractor(s) or for any forbearance, act of omission on the part of the Institute or any indulgence by the Institute to the said contractor(s) or by any such matter or thing whatsoever which under the law relating to sureties would, but for this provision, have effect of so relieving us.
6. This Guarantee will not be discharged due to the change in the constitution of the Bank or the contractor(s).
7. We(Name of the bank)..... lastly under take not to revoke the Guarantee except with the previous consent of the Institute in writing. This bank Guarantee on the Bank or its successors or permitted assigns.

8. We.....(Indicate the name of the Bank)..... lastly undertake not to revoke this

Guarantee except with (indicate the name of the Bank) the previous consent of the Institute extended on demand by the Institute. Notwithstanding anything mentioned above, our

Liability against this Guarantee is restricted to Rs.....(Rupees.....only), and unless a claim/demand is made on the bank in writing on or beforeall your rights under the Guarantee will be forfeited and we shall be relieved and discharged from all liabilities thereunder.

Authorized Signatories of the Bank with name and Seal

Name of the Officer:

Designation:

Code if any:

Date:

Place