

Project Name: Procurement of Equipment, Goods, Works and Services for Foundation for Innovative New Diagnostics (FIND), India under GFATM financed Project

Title of Consulting Services: Selection of Agencies for Providing Annual Maintenance Services for BSL-3 Lab Facility, BSC, Laminar Flow and other TB Laboratory Equipment under RNTCP, Ministry of Health & Family Welfare, Govt. of India

Amendment No.- 01

Dated :- 06.06.2016

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| 1. RFP Reference No. :- | SAMS/FIND/Lab Equip/AMC/1/2016 |
| 2. Date of Publication / Notification :- | 29.05.2016 |

Reference original RFP issued on 29th May, 2016, following amendments to the document are being made:-

Reference of RFP	Existing	As amended
1. Extension of date of Pre-Proposal Conference- Refer clause no. 3 of Bid Data Sheet of RFP		
Pre-Proposal Conference Date, Time and Place Page no.-16 of RFP	9th June, 2016 at 1500 hours at Strategic Alliance Management Services Pvt. Ltd. B01-B03, Vardhman Diamond Plaza, Community Centre, D. B. Gupta Road, Paharganj, New Delhi – 110055	13th June, 2016 at 1500 hours at Strategic Alliance Management Services Pvt. Ltd. B01-B03, Vardhman Diamond Plaza, Community Centre, D. B. Gupta Road, Paharganj, New Delhi – 110055
2. Evaluation Criteria: Refer clause no. 15 of Bid Data Sheet of RFP		
Evaluation Criteria: A (c) Page no.-18 of RFP	c. In-house calibration expertise/ long term agreement or tie up with reputed agencies for 3 rd party validation and owning certified master calibrators for validation and calibration of BSL3 lab/BSC and Laminar flow cabinet. The master calibrators must be certified in accordance with National/International standards. Agency must submit such list of Master Calibrator available with them along with valid certificates (to be filled in format at Annexure 4 under TOR) and copy of agreement with agencies for 3 rd party validation of BSL3 and BSCs- 5 Points	c. i. BSL 3 facilities/ Biosafety Cabinet/Laminar flow cabinet: In-house calibration expertise/ long term agreement or tie up with reputed agencies for 3 rd party validation and owning certified master calibrators for validation and calibration of BSL3 lab/BSC/Laminar flow cabinet. The master calibrators must be certified in accordance with National/International standard. Agency must submit copy of agreement with agencies for 3 rd party validation of BSL3 and BSCs. ii. For other TB lab equipment: In-house expertise and owning certified master calibrators from competent agency for calibration of TB lab equipments/having NABL accredited equipment testing labs (atleast 2-3 equipment involved in this proposal) Agency must submit such list of Master Calibrator for BSL 3 Lab/ BSC/Laminar flow cabinet and Other TB lab equipment available with them along with valid certificates (to be filled in format at Annexure 4 under TOR) - 5 Points

Reference of RFP	Existing	As amended
3. Terms Of Reference- Section-5		
Section-5 Terms of Reference	Terms of Reference from Page nos. 38-45 of RFP	The original Terms of Reference from Page nos. 38-45 of RFP may be treated as Deleted. <u>The revised Terms of Reference (TOR) under Section-5 is appended here.</u>

The Amended Terms of Reference (TOR)

Background

Global Fund for Aids, Tuberculosis and Malaria (GFATM) has given grant for equipping and maintaining of Laboratories for diagnosis of tuberculosis with Central TB Division, Ministry of Health & Family Welfare, Government of India as Principal Recipient (PR) and Foundation for Innovative New Diagnostics (FIND) as Sub Recipient (SR).

Strategic Alliance Management Services Pvt. Ltd. (SAMS) is acting as Procurement Agent to FIND for rendering Procurement Consultancy Services. SAMS, on behalf of FIND intends to engage agencies to carry out Annual Maintenance Services (AMC) for the BSCs & Laminar flow cabinets, BSL 3 Lab facility and TB Laboratory Equipment as per the GFR guidelines. The agency will be responsible for the services detailed under Preventive Maintenance (PM) Checklist (**Annexure 1**) including calibration and validation of the equipment available in individual laboratory as set out in each schedule (**Annexure 2**) as per terms & conditions of Contract.

Objective:

SAMS on behalf of FIND intends to hire the services of agencies to carry out AMC of the BSL3 Lab Facility, Bio Safety Cabinets (BSC), Laminar flow and other TB laboratory Equipment including PM, calibration and validation as specified in **Annexure 1**. The detailed inventory list of equipments installed in each of the Laboratory under relevant schedules is provided in **Annexure 3**.

Schedules and Categories of Equipment (Annexure 2 and 3):

The laboratories under Contract for AMC Services are divided in Schedules. There are total Thirteen Schedules. Schedules are made as per four regions of India for three different categories of equipment i.e. BSL3 Lab Facilities and Bio Safety Cabinets (BSC), Laminar flow and Medical Equipment respectively.

- Schedule I to IV comprises of AMC of BSL3 Lab Facilities.
- Schedules V to VIII comprises of AMC of Bio Safety Cabinets (BSC) and Laminar flow.
- Schedules IX to XIII comprised other TB Laboratory Equipment

The inventory of BSL 3 Lab Facility and Bio Safety Cabinets (BSCs), Laminar flow and other TB laboratory Equipment at each of the Laboratory is provided in **Annexure 3**. The bidders must submit their proposal considering all the labs/ inventory of equipment included in each Schedule. **The agency, based on their expertise and capacity, can apply for any or all schedules under RFP**

Tasks to be carried out:

On receipt of NOA/ Contract, the agency will carry out following tasks:

Scope of Work for AMC Services of BSL3 laboratories and TB Laboratory Equipment

1. To carry out AMC including Preventive Maintenance, calibration/ validation of BSL 3 facilities, Biosafety Cabinet, Laminar flow cabinet and TB laboratory equipment as per work flow process defined for breakdown calls and preventive maintenance in the TOR.
2. To share the PM/ Calibration/Validation schedule as well as the type of assistance required from the laboratory to the SAMS/FIND and designated representative of the laboratory and seek their convenience.
3. To ensure that the services are conducted as per Standard Operating Procedure with pre-defined manufacturer protocols.
4. To carry out maintenance of each equipment on the pre-defined protocols (to be shared with the laboratory) as per manufacturer's directions.
5. To carry out calibration of the parameters wherever specified against NABL ISO/IEC 17025 and ISO 15189-2012 Standards
6. To carry out the validation of BSL 3 facilities, Biosafety Cabinet and Laminar flow cabinet wherever specified as per WHO / International Standards
7. To prepare report after each visit and provide the activities carried out including the traceability of the standards used.

WORK FLOW PROCESS FOR BREAKDOWN CALLS FOR BSL 3 FACILITY, BIOSAFETY CABINET AND LAMINAR FLOW CABINET:

1. Agency shall be informed by lab /SAMS about any breakdown calls with, details of equipment and nature of breakdown.
2. The same complaint shall be copied to all concerned FIND officials (Regional Biomedical Engineer and Medical Officer of respective lab) also for needful support through mail. The same information shall also be available on Google Docs for reference of all concerned to minimize timelines on actions from different individuals. **Any other suggestion of participating agency for streamlining the complaint system and ways to minimize timelines for attending the breakdown calls is encouraged to be included in their proposal under methodology and work plan. Such suggestions will be given extra weightage in technical evaluation.**
3. Agency should provide their unique complaint log number for each breakdown call logged immediately or within one working day through an email communication and on Google doc.
4. Agency to contact the lab regarding the nature of breakdown of equipment and provide assistance for troubleshooting in a time bound manner based on the categorization as mentioned below and the same will be defined at the time of complaint logging by FIND:
 - a) Remote assistance should be provided within 24 hours of complaint logged
 - b) All Breakdown calls would be identified by FIND in the following categories on the day of complaint logging and after identification of category of complaint it should be resolved within time lines specified, as below;
 - i. Critical Calls: **within 5 working days** from the date of complaint categorization.
 - ii. Urgent Calls: **within 14 working days** from the date of complaint categorization.

- iii. Normal Calls: **within 21 working days** from the date of complaint categorization.
 - iv. Other Calls: any call not identified under above categories should be attended by agency at the earliest possible or during any interim visit for PM or attending breakdown call visit, whichever earlier.
5. For any visit to lab for rectification of the breakdown, agency should intimate through an email communication to Lab, SAMS, concerned FIND officials (Regional Biomedical Engineer and Medical Officer of respective lab) regarding visit of service engineer, date and other requirements, if any
 6. Agency during the period of contract should come up with a price list of common parts being procured for break down call along with quotes and/or invoices, so that FIND could consider having a pre-approved rate list to minimize the time required for financial approval at its end.
 7. Agency should also maintain good coordination with manufacturer of equipment under Contract (Refer Inventory) to ensure availability of spare parts from any manufacturer as and when required. They should also keep updated standard price list of spares of all manufacturers of equipment under AMC Contract.
 8. If any spare part is required for resolving the breakdown complaint, agency should submit quote for approval to SAMS in the manner as mentioned below;
 - a. If the spare part is in the pre-approved rate list, the approval to go ahead will be provided within a day
 - b. Agency needs to submit quote for spares beyond the pre-approved list from respective original equipment manufacturer for approval of SAMS/FIND, confining to the timeline of resolving the issue as mentioned above in point no. 4
 - c. Agency should submit minimum three quotations for approval for which manufacturer is not available or spare is not available from manufacturer, confining to the timeline of resolving the issues as mentioned above in point no.4. the effort should be made both
 - d. Quotations to be submitted for approval in a time bound manner in order to ensure that the breakdowns can be rectified in a time bound manner in line with point 4
 - e. Any delay in the prescribed timelines, should be upfront intimated to FIND in a time bound manner (in line with timelines described in point 4) with justification for delays, seeking an approval from FIND/SAMS on alternate timelines, on case to case basis
 - f. If the cost of spare part to be replaced is within Rs.5000, then agency may change spare instantaneously arranging from local supplier / from authorized agency/ manufacturer after approval from SAMS/ FIND regional team No need of submitting quotations and PO from SAMS in such cases.
 9. Once the problem has been resolved, agency should send an email communication for call closure within one working day to Lab, SAMS and FIND officials.
 10. Service Report to be submitted for each call attended and completed to Lab Manager on the day call is attended and within five working days to FIND-SAMS.
 11. Service report should flag any irreparable equipment available in lab and justification letter should be submitted for the same by agency.
 12. Agency should submit the standard operating procedures for breakdown service and troubleshooting to FIND and SAMS
 13. Selected agency to submit the breakdown service report format to FIND and SAMS for review and approval on receipt of NOA for undertaking the AMC services
 14. The agency should provide both verbal and written guidance to the lab on ways to minimize the given break-down.

15. Agency should submit status report of breakdown call in standard format on weekly basis to FIND and SAMS.
16. Agency should have Field Service Engineers based regionally (Specially four regions: North, East, West and South), or for the applied regions.

PREVENTIVE MAINTENANCE AND CALIBRATION/VALIDATION OF BSL 3 FACILITY, BIOSAFETY CABINET AND LAMINAR FLOW CABINET

1. Agency should submit Preventive Maintenance (PM)/ calibration/ Validation schedule for each lab in advance for approval of SAMS/ FIND. The first PM/calibration/ validation schedule should be in sync with previous PM and validation date of completion of BSL 3 facility, BSC and Laminar flow of each lab
2. Agency has to carry out PM and validation visit as specified below;
3. Annual preventive maintenance and annual validation should be carried out for all BSL 3 facilities, Biosafety Cabinet and Laminar Flow Cabinet covered under the contract
4. Validation for BSL 3 facility, BSCs and Laminar Flow should also be done whenever any repair work such as HEPA filter replacement, blower replacement is carried out.
5. For preventive maintenance call; Agency should intimate concerned labs, SAMS and FIND officials (Regional Biomedical Engineer, Regional Microbiologist and Medical Officer of respective lab) through an email communication regarding the scheduled preventive maintenance visit to lab as per contract.
6. During first preventive maintenance visit, agency should carry out initial inspection of BSL 3 facilities, Biosafety Cabinet and Laminar flow cabinet equipment as per prescribed jobs annexed and submit report for the services carried out.
7. In case there is any change in PM Visit as per schedule, Agency should intimate in advance to the Lab and confirm the date keeping FIND and SAMS in loop.
8. Agency should carry out service and maintenance of BSL 3 facilities, Biosafety Cabinet and Laminar flow cabinet in line with the standard operating procedures, with pre-defined service protocols and as per manufacturer's directions.
9. Agency should submit the Standard Operating Procedures for Preventive Maintenance / calibration/ Validation of BSL 3 facilities, Biosafety Cabinet and Laminar flow cabinet to FIND and SAMS within one month of the Award of Contract for AMC services.
10. Agency to submit the Preventive Maintenance report, calibration report, validation and PM checklist format to FIND and SAMS for review and approval within fifteen (15) days of receipt of NOA for undertaking the AMC services
11. Agency should carry out calibration of the parameters wherever specified meeting the prescribed National/ International Standards as per manufacturer's directions.
12. Agency should carry out the validation of equipment wherever specified as per WHO / International Standards and manufacturer's directions
13. Agency should submit PM report along with checklist (standard as annexed) suggesting activities carried out for the equipment during visit, calibration report with traceability certificates of standards used for each equipment
14. PM report-checklist should be signed and stamped by Lab Manager on each page and submitted to Lab Manager on the day of completion of PM activities onsite and within five working days to FIND and SAMS
15. Calibration report and validation report should be submitted within five working days to Lab Manager, FIND and SAMS.
16. Agency should share in advance about any type of assistance required from the laboratory for conduction PM/ Calibration at their labs.

17. Agency to submit the list of master instrument for calibration and validation along with valid traceability certificates to FIND and SAMS within one month of Award of Contract for AMC Services.
18. Any break-down/malfunction equipment noticed during the PM visit should be reported to Lab, FIND and SAMS along with service report by agency and corrective action may be taken during PM visit only.
19. Agency should provide training to their staff attending the preventive maintenance and breakdown calls for handling particular equipment. In the inception report of contract, agency should submit their plan to take care of issues when trained staff carrying out activities leaves their organization.
20. The PM report should flag any irreparable equipment available in lab and justification for same should be submitted.
21. The approval for extending the timelines/ approved Pm schedule will be required prospectively in each case. No retrospective approval will be considered for waiving the penalty (Liquidated damages). So any request for extension in timelines should be informed with full justification and approvals must be obtained for the same.

Workflow Process for Breakdown Calls for TB Lab Equipment

1. Agency shall be informed by lab /SAMS about any breakdown calls with, details of equipment and nature of breakdown.
2. The same complaint shall be copied to all concerned FIND officials (Regional Biomedical Engineer and Medical Officer of respective lab) also for needful support through mail. The same information shall also be available on Google Docs for reference of all concerned to minimize timelines on actions from different individuals. **Any other suggestion of participating agency for streamlining the complaint system and ways to minimize timelines for attending the breakdown calls is encouraged to be included in their proposal under methodology and work plan. Such suggestions will be given extra weightage in technical evaluation.**
3. Agency should also provide their unique complaint log number for each breakdown call logged immediately or within one working day through an email communication and on Google doc.
4. Agency to contact the lab regarding the nature of breakdown of equipment and provide assistance for troubleshooting in a time bound manner based on the categorization as mentioned below and the same will be defined at the time of complaint logging by FIND:
 - a) Remote assistance should be provided within 24 hours of complaint logged
 - b) All Breakdown calls would be identified by FIND in the following categories on the day of complaint logging and after identification of category of complaint it should be resolved within time lines specified, as below;
 - i. Critical Calls: **within 5 working days** from the date of complaint categorization.
 - ii. Urgent Calls: **within 14 working days** from the date of complaint categorization.
 - iii. Normal Calls: **within 21 working days** from the date of complaint categorization.
 - iv. Other Calls: any call not identified under above categories should be attended by agency at the earliest possible or during any interim visit for PM or attending breakdown call visit, whichever earlier.
5. For any visit to lab for rectification of the breakdown, agency should intimate through an email communication to Lab, SAMS, concerned FIND officials (Regional Biomedical

- Engineer and Medical Officer of respective lab) regarding visit of service engineer, date and other requirements, if any
6. Agency during the period of contract should come up with a price list of common parts being procured for break down call along with quotes and/or invoices, so that FIND could consider having a pre-approved rate list to minimize the time required for financial approval at its end.
 7. Agency should also maintain good coordination with manufacturer of equipment under Contract (Refer Inventory) to ensure availability of spare parts from any manufacturer as and when required. They should also keep updated standard price list of spares of all manufacturers of equipment under AMC Contract.
 8. If any spare part is required for resolving the breakdown complaint, agency should submit quote for approval to SAMS in the manner as mentioned below;
 - a) If the spare part is in the pre-approved rate list, the approval to go ahead will be provided within a day
 - b) Agency needs to submit quote for spares beyond the pre-approved list from respective original equipment manufacturer for approval of SAMS/FIND, confining to the timeline of resolving the issue as mentioned above in point no. 4
 - c) Agency should submit minimum three quotations for approval for which manufacturer is not available or spare is not available from manufacturer, confining to the timeline of resolving the issues as mentioned above in point no.4
 - d) Quotations to be submitted for approval in a time bound manner in order to ensure that the breakdowns can be rectified in a time bound manner in line with point 4
 - e) Any delay in the prescribed timelines, should be upfront intimated to FIND in a time bound manner (in line with timelines described in point 4) with justification for delays, seeking an approval from FIND/SAMS on alternate timelines, on case to case basis
 - f) If the cost of spare part to be replaced is within Rs.5000, then agency may change spare instantaneously arranging from local supplier / from authorized agency/ manufacturer after approval from SAMS/ FIND regional team No need of submitting quotations and PO from SAMS in such cases.
 9. Once the problem has been resolved, agency should send an email communication for call closure within one working day to Lab, SAMS and FIND officials.
 10. Service Report to be submitted for each call attended and completed to Lab Manager on the day call is attended and within five working days to FIND-SAMS.
 11. Service report should flag any irreparable equipment available in lab and justification letter should be submitted for the same by agency.
 12. Agency should submit the standard operating procedures for breakdown service and troubleshooting to FIND and SAMS
 13. Selected agency to submit the breakdown service report / Calibration report format to FIND and SAMS for review and approval on receipt of NOA for undertaking the AMC services
 14. The agency should provide both verbal and written guidance to the lab on ways to minimize the given break-down.
 15. Agency should submit status report of breakdown call in standard format on weekly basis to FIND and SAMS.
 16. Agency should have Field Service Engineer based regionally (Specially four regions: North, East, West and South) or for the applied regions.

Workflow Process for Preventive Maintenance and Calibration for TB Lab Equipment

1. Agency should submit Preventive Maintenance (PM)/ calibration/ Validation schedule for each lab in advance for approval of SAMS/ FIND. The first PM/calibration/ validation schedule should be in sync with previous PM /calibration/ validation date of completion of lab equipment of each lab
2. Agency has to carry out PM and calibration visit as specified below;
 - a) Annual PM and annual calibration should be carried out for all equipment covered under the contract
 - b) For Pipettes and Centrifuges, PM and calibration should be done on six monthly basis
3. For preventive maintenance call; Agency should intimate concerned labs, SAMS and FIND officials (Regional Biomedical Engineer and Medical Officer of respective lab) through an email communication regarding the scheduled preventive maintenance visit to lab as per contract.
4. During first preventive maintenance visit, agency should carry out initial inspection/ calibration of each equipment as per prescribed jobs annexed and submit report for the services carried out.
5. In case there is any change in PM Visit as per schedule, Agency should intimate in advance to the Lab and confirm the date keeping FIND and SAMS in loop.
6. Agency should carry out service and maintenance of each equipment in line with the standard operating procedures, with pre-defined service protocols and as per manufacturer's directions.
7. If any equipment is required to be taken out for calibration, it should be taken in two tranches(approx 50% quantity in each) depending upon the workload of the labs and should be returned within 10 days to the lab and proper record should be maintained by agency and information should be shared immediately with FIND and SAMS.
8. Agency should submit the Standard Operating Procedures for Preventive Maintenance / calibration of equipment to FIND and SAMS within one month of the Award of Contract for AMC services.
9. Agency to submit the Preventive Maintenance report, calibration report and PM checklist format to FIND and SAMS for review and approval within fifteen (15) days of receipt of NOA for undertaking the AMC services
10. Agency should carry out calibration of the parameters wherever specified to meeting the prescribed National/ International Standards as per manufacturer's directions.
11. Agency should submit PM report along with checklist (standard as annexed) suggesting activities carried out for the equipment during visit, calibration report with traceability certificates of standards used for each equipment
12. PM report-checklist should be signed and stamped by Lab Manager on each page and submitted to Lab Manager on the day of completion of PM activities onsite and within five working days to FIND and SAMS
13. Calibration report should be submitted within five working days to Lab Manager, FIND and SAMS.
14. Agency should share in advance about any type of assistance required from the laboratory for conduction PM/ Calibration at their labs.
15. Agency to submit the list of master instrument for calibration and validation along with valid traceability certificates to FIND and SAMS within one month of Award of Contract for AMC Services.

16. Any break-down/malfunction equipment noticed during the PM visit should be reported to Lab, FIND and SAMS along with service report by agency and corrective action may be taken during PM visit only.
17. Agency should provide training to their staff attending the preventive maintenance and breakdown calls for handling particular equipment. In the inception report of contract, agency should submit their plan to take care of issues when trained staff carrying out activities leaves their organization.
18. The PM report should flag any irreparable equipment available in lab and justification for same should be submitted.
19. The approval for extending the timelines/ approved Pm schedule will be required prospectively in each case. No retrospective approval will be considered for waiving the penalty (Liquidated damages). So any request for extension in timelines should be informed with full justification and approvals must be obtained for the same.

Duration of the Assignment/ Contract

1. The duration of the assignment/contract will be for one year initially which may be extended annually upto three years or as per the project needs based on satisfactory performance of the agency.
2. The number of labs under each schedule may be increased or decreased as per project needs. More labs could be added in any schedule as and when required on the pro-rata basis during the Contract period.
3. The equipments which are currently under warranty and is not included in the current inventory list shall be added under AMC Contract for all labs under each Schedules after end of the warranty period of those equipments. However, need based PM & repairs on the request of FIND, of these equipments under warranty fall within the scope of the current contract, at no additional costs, apart from costs of spares.
4. The inventory list (Annexure 3) is not exhaustive and may be subject to additions as per laboratory requirement for which point no. 3 above would apply.

Deliverables/ Reporting

1. The agency shall issue Service/ PM/ Calibration Reports, immediately after the completion of activities, to the Laboratory with copies to FIND, In-charge Procurement-SAMS and any other agency as directed by SAMS.
2. Agency shall submit monthly report in the standard format on the status of breakdown calls and PM/ Calibration visits.

Schedule for completion of tasks:

1. The agency will have to initiate the services within 15 days of receiving of NOA.
2. The agency will have to complete the annual PM/ calibration visit at all labs under Contract within 6 months of the issue of NOA in accordance with existing PM due dates.
3. Unlimited nos. of breakdown calls from any labs under Contract, as and when required should be attended promptly and closed as per timelines given under work flow **process for breakdown calls for both BSL-3 facilities and TB laboratory equipment(s). (Sl. No. 4).**

Data to be provided by the SAMS

1. SAMS shall provide detailed scope of work, details and quantity of equipment to be serviced, location, contact details of lab In-Charge to Agency.
2. Any other support required for initiating the services.

Assistance to be provided by the Laboratory

The Laboratory would facilitate the agency for carrying out the AMC / required activities in their working days in office hours.

Review of the Agency work

The performance of the Agency will be reviewed by SAMS/ FIND from time to time. If the performance of the Agency is found to be unsatisfactory at any time during the tenure, the contract of the agency may be cancelled. The following is list of parameters which will be considered while reviewing the performance of agency:

- a) Time taken by agency to initiate the job work / visit for breakdown call
- b) Time taken by agency to complete each of the breakdown call
- c) No. of breakdown calls closed within the prescribed timelines
- d) Time taken by agency for closing the breakdown calls in critical calls
- e) Time taken by agency to issue reports after completion of all activities
- f) Incidences of non-satisfactory performance reported from the laboratories
- g) PM schedule adherence
- h) Completion of PM visit within prescribed timelines

Payment terms

Payments shall be made according to the following schedule:

Lump Sum Contract Cost is divided against two major deliverables under AMC Contract i.e. **Preventive Maintenance- 40% of Contract Cost** and **other AMC/repair Services-60% of Contract cost.**

Payment Schedule:

1. **15% advance** of total Contract cost upon submission of following documents:
 - Signed Contract
 - Submission of Performance Bank Guarantee (PBG) for the amount of 5% of Contract cost. This PBG should remain valid for fourteen (14) months from the date of Contract.
 - Another Bank Guarantee against advance payment of 15% of Contract cost with the validity of minimum eight (8) months from the date of contract.
 - BGs should be submitted within 21 days of signing of the Contract.
 - The BG against advance payment shall be released when the advance payment has been fully set off.
- a. **40% of Contract Cost** on completion of PM/ calibration/validation services on pro-rata basis supported by relevant documents against each labs.
- b. **60%** on completion of other AMC and repair services supported by relevant documents **on quarterly basis (15% every quarter against AMC/ repair services).**

LIST OF KEY PROFESSIONALS AND THEIR QUALIFICATION & EXPERIENCE REQUIREMENTS:

Agency should have minimum following no. of officials working on full time basis for each Schedule quoted:-

Sl. No.	Key Position	Professional Qualification	Experience Desired	No. of Staff required per schedule of BSL3 (I-IV)	No. of Staff required per schedule of BSC, LF and other TB laboratory equipment (V-XIII)
1	Team Leader*	B. Tech in Bio Medical Instrumentation/B.Sc. or M.Sc. in medical Instrumentation or electronics (preferable) / B. Tech (any stream)/ B.Sc./ M.Sc. in Microbiology, Physics or equivalent	Minimum seven years relevant Experience in maintenance, Calibration and Validation of lab equipment/ BSL-3/ Clean room as per National/ International standards out of which he/she preferably should have three to five years of experience at senior manager position and/or experience of leading/ management of one similar project.	One* (1)	One* (1)
2	Bio-medical Engineer/ Service Engineer	B. Tech in Bio Medical Instrumentation/ Diploma or B.Sc. or M.Sc. in medical Instrumentation or electronics (preferable) / B. Tech (any stream)/ B.Sc./ M.Sc. in Microbiology, Physics or equivalent	Minimum three years (for diploma holders five years) of relevant Experience in Maintenance, Calibration and Validation of lab equipment as per National/ International standards.	One (1)	One (1)
3	Field Service Engineer (Maintenance and Calibration of analytical equipment)	B. Tech in Bio Medical Instrumentation/ Diploma or B.Sc. or M.Sc. in medical Instrumentation or electronics/ B. Tech (any stream)/ B.Sc./M.Sc. in Microbiology, Physics or equivalent, ITI/ Diploma in relevant subject with minimum five years of relevant experience.	Minimum three years (five years for ITI /diploma) of relevant Experience in maintenance, Calibration and Validation of lab equipment/ BSL-3/ Clean Room as per National/ International standards.	Two (2)	One (1)

***Consultant may propose only one team leader up to any four schedules quoted.**

Note: -

- If the agency is submitting proposal for more than one or all Schedules, the agency must propose key officials for executing this project in multiple of above nos. with no. of Schedules quoted, except team leader*.

- Qualification/experience of the team described in TOR is only “desirable” and the invited consultant may propose the team as they deem fit with better qualification.
- The number of staff will need to be increased on prorata basis and need, in case of addition of work load of additional labs

Reference of RFP	Existing	As amended
3. Annexure-1 (under Section-5- Terms Of Reference)		
Annexure-1 Page no. 46	PREVENTIVE MAINTENANCE AND CALIBRATION CHECKLIST	<p><u>Following Paras are added (amendment) under Annexure-1</u></p> <p>Checklist for PM and Calibration for BSL-3 lab facilities, BSCs and Laminar Flow Cabinets is being added, appended herewith from Sl. 1 to 3</p> <p>The sl. Nos. of remaining items in the checklist shall be shifted accordingly in the RFP</p>

Following Paras are added (amendment) under Annexure-1 of Section-5, Terms of Reference)

PREVENTIVE MAINTENANCE AND CALIBRATION CHECKLIST

DETAILED PREVENTIVE MAINTENANCE AND CALIBRATION ACTIVITIES TO BE CARRIED OUT FOR BIOSAFETY CABINET, LAMINAR FLOW CABINET AND BSL 3 TB CONTAINMENT FACILITIES AND OTHER TB LABORATORY EQUIPMENT

1. Bio Safety Cabinet:

- Complete and thorough cleaning of working Area of cabinet and below it.
- Cleaning and oiling of sliding sash movement system.
- Checking of switches, tube lights and UV light fittings.
- Checking of airflow and exhaust system
- Calibration and validation of Magnehelic Gauges if existing
- Validation of BSC: Particle count test, PAO Filter Integrity test for HEPA filters), Air inflow velocity and downflow velocity test as per NSF 49 and EN 12469 standards with devices traceable to National / International Standards.
- Checking general performance of unit.
- Checking of overall operation of the unit
- BSC should be checked by end user once maintenance and calibration activities are completed
- Inspection of exhaust blower motor and its fan
- Inspection of ducting for any breach/damage.

2. Laminar Flow

- Complete and thorough cleaning of working Area of Laminar Flow.
- Cleaning of pre filters
- Cleaning and oiling of sliding sash movement system.
- Checking of switches, tube lights and UV light fittings.
- Checking of airflow and exhaust system

- Validation: Particle count test, PAO (Filter Integrity test for prefilters, HEPA filters), downflow velocity as per ISO Class 5, with devices traceable to National / International Standards.
- Periodic checking of airflow velocity, uniformity, static pressure, etc. should be done
- Checking general performance of unit.
- Checking of overall operation of the unit
- Laminar Flow should be checked by end user once maintenance and calibration activities are completed

3. BSL 3 TB Containment Lab: All the certification and validation parameters for TB Containment Lab must be done in accordance with NIH certification requirement. The installation as a whole shall be balanced, tested and validated, and all relevant information, including the following shall be submitted to the Institution and hiring agency

Complete servicing and maintenance of BSL 3 lab will be carried out including

- Electrical current readings, in amperes on full load work, average running, and on starting, Testing of power cabling, earthing, AHU control panel, MCCB panel and LT panels
- Cleaning of pre filters (G4)
- Replacing of filters if integrity lost
- Wet servicing of DX unit
- Servicing of the motors (supply, exhaust, BSC exhaust duct) along with belt tightening/ replacement
- Containment room -the walls, floors, ceilings, penetrations, and other containment barrier features have adequate integrity (using sealing agent, etc.)
- Servicing of all existing doors and testing of alarm system for emergency door
- Servicing and repair of split AC in BSL 3 facility (dedicated for MGIT 960 only).
- UV Lamp to be cleaned and replaced if their life cycle is near completion.

Following testing should be performed:

1. Air inflow velocity and outflow velocity test across all inlets and outlets to measure/derive air change rate per hour (minimum 6-12 ACH)
2. Smoke pattern test for directional airflow should be performed during validation.
3. Temperature shall be maintained at 22°C±2 and humidity level should be maintained at 60±10%
4. Pressure monitoring device (Analog and Digital); differential pressure check (at least -0.05 in WG (-12.5 Pa) should be maintained from clean areas to more contaminated areas). In no case, should the differential be less than -0.03 in. WG (-7.6 Pa) when the door is closed between BSL3 and Ante Room.
5. HEPA Filter (in BIBO) integrity test based on EN1822 at MPPS (Maximum Penetrating Particle Size) through particle count test and PAO test and manufacturer's certifications

Operational performance testing for

- a) HVAC including Blower motors in the Supply, exhaust including emergency, extractor of BSC ducting and condensation unit.
- b) Ducting for any potential leakages and insulation breakage
- c) Dampers including variable control, leak proof and fire control (only verification)
- d) Magnehelic Gauges

- e) Temperature control sensors; pressures control sensors,
- f) Split ACs
- g) Fire Detection system
- h) EPABX System
- i) Access Control System
- j) CCTV System
- k) UPS Back up system
- l) Emergency Shower and eye wash station

End user should check once service and calibration/Validation activities are completed.

Important Note to be followed by Agency:

- a. Manufacturer protocols should be followed for Maintenance and Service
- b. End user should check all the equipment once preventive maintenance and validation activities are completed by Service Engineer before signing the PM report
- c. Manufacturer protocols, NABL/National/International standards should be followed for calibration and validation
In case of any deviation in calibration and validation parameter of any equipment, recalibration and validation should be performed.

The above amendments are integral part of the original RFP and shall be applicable to all relevant sections of the referred bid. Kindly prepare and submit your bids accordingly.

For Strategic Alliance Management Services Pvt. Ltd.



**Jyoti Singh
Sr. Manager (Procurement)**