



Request for Proposal # 2021-069
for
Consultancy Services to assist Five Laboratories in Private Sector in Obtaining NABL Accreditation for Assay (Purity) of Medical Grade Oxygen as per ISO/IEC 17025:2017

I. Summary of Deadlines

Release of Request for Proposal (RFP)	29-Dec-21
Confirmation of interest due	07-Jan-22
Request for clarifications received by	07-Jan-22
Response to Request for clarifications	12-Jan-22
Due date and time of proposal submission	21-Jan-22 up to 2400 hrs
Proposal Evaluation completed	28-Jan-22
Consultants notified of decision	2-Feb-22

Note that PATH reserves the right to modify this schedule as needed. All parties will be notified simultaneously by email of any changes.

II. PATH Statement of Business

PATH is the leader in global health innovation. An international non-profit organization, PATH saves lives and improves health, especially among women and children. PATH accelerates innovation across five platforms—vaccines, drugs, diagnostics, devices, and system and service innovations—that harness our entrepreneurial insight, scientific and public health expertise, and passion for health equity. By mobilizing partners around the world, PATH takes innovation to scale, working alongside countries primarily in Africa and Asia to tackle their greatest health needs. Together, we deliver measurable results that disrupt the cycle of poor health. Learn more at www.path.org.

III. Project background of RFP

PATH is supporting USAID’s Reaching Impact, Saturation, and Epidemic Control (RISE) Project in building resilient and responsive health systems for management of COVID-19. The goal of the



project is to attain and maintain epidemic control, with stronger local partners capable of managing and achieving results through sustainable, self-reliant, and resilient health systems by improving surveillance, rapid response, and emergency operations. The activities under the project shall build and upgrade capacities of critical workforce and decision makers for maintenance, operationalization of oxygen infrastructure, hygienic use of oxygen and respiratory care equipment for successful administration of medical oxygen therapy.

Under this project, PATH is strengthening the oxygen ecosystem in 20 states of India (Andhra Pradesh, Assam, Chhattisgarh, Delhi, Goa, Gujarat, Haryana, Himachal Pradesh, Jharkhand, Karnataka, Kerala, Madhya Pradesh, Maharashtra, Odisha, Punjab, Rajasthan, Tamil Nadu, Telangana, Uttarakhand and West Bengal) by supporting the hub facilities through the following interventions:

- Strengthen facility-level oxygen management, operation, and maintenance through an end-to-end technical assistance support to hub facilities;
- Demystifying regulatory framework by developing standard operating procedures and providing need based technical support for PESO compliance and certification for oxygen sources and facilities and demonstrate a model for scaling up to other facilities;
- Build capacities of the healthcare workers and key decision makers through training to hub facilities on critical aspects such as oxygen ecosystem, operation and maintenance of PSA plants and other oxygen equipment, rational and hygienic use of oxygen, monitoring of PSA post operationalization, oxygen quality testing protocols;
- Strengthen access to oxygen testing by creating a network of NABL accredited gas analysing labs to do quality testing of oxygen produce at intervention facilities; and
- Ensure documentation of key learnings from the initiative, SOPs, guidance material and dissemination of this knowledge through hub level trainings.

Beyond these interventions, PATH will support two additional hubs – the All India Institute of Medical Sciences (AIIMS), Patna and North Eastern Indira Gandhi Regional Institute of Health & Medical Sciences (NEIGRIHMS), Shillong – through the RISE project to conduct trainings for their spokes.

In order to implement the project, PATH plans to procure consultancy services to facilitate five Laboratories in Private Sector in obtaining NABL Accreditation for Assay (Purity) of Medical Grade Oxygen as per ISO/IEC 17025:2017.

IV. Selection Process

Technical and Financial Proposals are invited by PATH. Consultants are advised to study the RFP Documents carefully. Proposals not complying with all the given clauses in this RFP Documents or failure to furnish all information required by the RFP Documents or submission of a proposals not substantially responsive to the RFP Documents in every respect will be at Consultant’s risk and may result in the rejection of proposal.

V. Proposal Submission

- A. Proposal must contain the complete address of firm, including contact number / email address of the person who is authorized to submit the proposal with his/her signatures.
- B. Un-signed proposals shall not be accepted.
- C. All pages of the proposal being submitted must be signed and sequentially numbered by the Consultant irrespective of the nature of content of the documents.
- D. Proposals not submitted as per the specified format and nomenclature will be liable to be rejected.
- E. Ambiguous proposals will be out rightly rejected.
- F. The interested consultants may submit their proposal to PATH on or before the time mentioned in this RFP Documents.
- G. PATH will not be responsible for any delay on the part of the Consultants in submission of the proposals. Any proposal received by PATH after the prescribed deadline for submission of proposal will be summarily rejected. No further correspondence in this regard will be entertained.
- H. Financial proposal should be prepared as per format with the RFP Documents.
- I. Proposals complete in all respects and associated documents, must be submitted through email up to the due date and time as per Section XI. No physical document is to be submitted by the Consultants.
- J. At any time prior to the last date for submission of proposals, PATH, may, for any reason, whether at its own initiative or in response to a clarification requested by a prospective Consultants, modify the RFP Documents by an amendment. Such amendments shall be sent to prospective Consultants who have shown their interest to submit proposal or submitted request for clarifications, through email.
- K. Proposals not prepared as per the format given by PATH will be liable to be rejected.
- L. Printed terms and conditions of the Consultants will not be considered as forming part of their proposal. In case terms and conditions as given in the RFP Documents are not acceptable to any consultant, they should clearly specify the deviations in their proposal.

VI. Proposal Requirements - Financial

The Consultant should quote lump-sum Consultancy Charges exclusive of GST (if applicable) for complete set of services at each lab (as per Scope of Services – Annexure E) as per the format given in Annexure D

VII. Schedule for completion of Services



The Services as per Scope of Services - Annexure E should be completed within 120 days of issue of Work Order (WO).

VIII. Payment Schedule

The payment shall be released within 30 days of submission of claim as per following schedule:

- A. 20% upon submission of completion of Gap Assessment at all the five laboratories and submission of Gap Assessment Reports.
- B. Reimbursement of Application Fee paid by the Consultant to NABL, and other expenses on account of travel, boarding and honorarium NABL's Assessors as per NABL's approved rates/policies.
- C. 30% after final assessment / audit by NABL
- D. 50% after receiving NABL Accreditation Certificate

IX. Proposal Requirements – Technical

A. Consultant eligibility requirements:

1. Consultant should be a legal entity for doing business in India.
2. Consultant should have successfully provided consultancy services to at least 5 (five) chemical / biological laboratories in getting NABL Accreditation of during last 5 years, as on due date for submission of proposals. Such laboratories should have secured NABL Accreditation.
3. The approach, methodology and work plan submitted by the consultant is found substantially responsive to the requirements stated in Scope of Services – Annexure E.
4. The Consultant should have at least one trained / certified / authorized trainer for imparting ISO/IEC 17025:2017 & NABL Accreditation Training. Such a trainer should have attended / passed course on ISO 17025 conducted by any Institution as per NABL requirement.

B. Documents Comprising Proposal:

Proposal submitted by a Consultant shall include the following:

1. Letter of Proposal (as per Annexure A).
2. Particulars of Consultant (as per Annexure B).
3. Approach, methodology and work plan (as per Annexure C).
4. Financial Proposal (as per Annexure D).
5. Mandatory enclosures along with the proposal as follows:
 - a) Copy of registration documents/certificate as a legal entity in India.

- b) Detailed CV of at least one trained / certified / authorized trainer / Auditor/ Lead Auditor for imparting ISO/IEC 17025:2017 & NABL Accreditation Training. The copy of certificate issued by Institution as per NABL requirement as an evidence of having been attended / passed course on ISO 17025 should also be submitted.
- c) Copy of Contract(s) / Work Order(s) issued by Clients (with copy of NABL Certificates) issued during last 5 years, as on the due date for submission of proposals.
- d) Copy of GST Registration Certificate.
- e) Audited balance sheet and audit report for 3 financial years (2018-19, 2019-20 & 2020-21).
- f) Certificate of Annual Turnover for financial years 2018-19, 2019-20 & 2020-21, issued by statutory auditor / chartered accountant.

X. Proposal Evaluation Criteria

A. Proposal evaluation process:

1. Proposals will be reviewed to determine completeness of proposal (based on the RFP Documents) and fulfilment of eligibility requirements of consultants. Proposals that do not meet eligibility requirements will be eliminated following this review and not be considered further.
2. All proposals received by the stated closing date and time for proposal submission will be evaluated and ranked according to the conditions described in evaluation criteria below.
3. The proposals will be evaluated based on the prices quoted for complete scope of services (as per Annexure E). The final selection will be on the least cost selection basis subject to verification of documents and technical evaluation of the proposals.
4. Successful consultant will be notified in writing by email. Consultant must confirm acceptance in writing within the time specified in the email.



B. Evaluation criteria:

1. The consultants who substantially conform to the “Proposal Requirements – Technical” (Section IX) shall be determined as technically qualified consultants.
2. The total prices for all the works given in Annexure E as quoted by such technically qualified consultants shall be evaluated and compared.
3. PATH may request the technically qualified consultants to make a detailed presentation on methodology and work plan for execution of services. The adequacy of methodology and work plan as assessed during presentation shall have bearing on final determination of bidder’s technical qualification.
4. The Consultant found technically qualified and quoted lowest cost shall be considered for issue of work order.

NOTE: PATH reserves the right to reject proposals that do not meet eligibility or proposal submission requirements (as detailed above) without further notice to the consultants. Issuance of this RFP does not constitute a commitment on the part of PATH nor does it commit PATH to pay for the costs incurred in submission of proposal. Further, PATH reserves the right to reject any or all proposals received and to negotiate separately with a consultant, if such action is considered to be in the best interest of PATH.

XI. Instructions and Deadlines for Responding

A. PATH contacts:

Any communication must be sent to rfpindia@path.org:

B. Confirmation of interest:

Please send a statement acknowledging receipt of this solicitation and your intent to respond or not respond no later than due date given in Section I. Send the confirmation to the contact listed above.

C. Request for clarifications:

Request for clarifications / questions on this solicitation will be accepted via email given above by due date given in Section I. Questions and answers will be provided to all prospective consultants who confirmed interest. Please note that responses will not be confidential except in cases where proprietary information is involved. Inquiries after this date cannot be accommodated.

D. Due date and time of Proposal Submission:

Submit your completed proposals by email to rfpindia@path.org latest by 24:00 Hrs. on 21/01/2022. The subject line of the email should read: “RFP # 2021-069 - Your Company Name”.

We advise that consultants send files in commonly recognized Microsoft formats. We will not accept responsibility for resolving technical transmission problems with proposals. A hard copy of the



proposal should not be sent. Your proposal should only include information specific to accomplishing the scope of work. Additional information submitted outside of the proposal requirements will be reviewed at PATH's discretion only.

E. Selection of Consultant

PATH reserves the right to select from among the proposals received. PATH has the option to seek additional information / documents and discuss specific details with those consultants who have submitted their proposals.

F. Receipt, Evaluation and Handling of Proposals

Once a proposal is received before the due date and time, the PATH will:

1. Log the receipt of the proposal and record the business information.
2. Review all proposals and disqualify any non-responsive ones (that fail to meet the terms set out in RFP Documents) and retain the business details on file with a note indicating disqualification.
3. Evaluate all proposals objectively in line with the criteria specified in the RFP Documents.
4. Inform consultants within timelines as per RFP of the evaluation decision being made.

G. General Disclosures

1. Consultants must disclose:

- a) If they are or have been the subject of any proceedings or other arrangements relating to bankruptcy, insolvency or the financial standing of the bidders including but not limited to the appointment of any officer such as a receiver in relation to the Bidder personal or business matters or an arrangement with creditors or of any other similar proceedings.
- b) If they have been convicted of, or are the subject of any proceedings, relating to:
 - i. Criminal offence or other offence, a serious offence involving the activities of a criminal organization or found by any regulator or professional body to have committed professional misconduct.
 - ii. Corruption including the offer or receipt of any inducement of any kind in relation to obtaining any contract with PATH, or any other contracting body or authority.
 - iii. Failure to fulfil any obligations in any jurisdiction relating to the payment of taxes.

XII. Terms and Conditions of the Solicitation
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A. Notice of non-binding solicitation

PATH reserves the right to reject any and/or all proposals received in response to this solicitation and is in no way bound to accept any proposal.

B. Confidentiality

All information provided by PATH as part of this solicitation must be treated as confidential. In the event that any information is inappropriately released, PATH will seek appropriate remedies as allowed. Proposals, additional information / documents, discussions, and all information received in response to this solicitation will be held as strictly confidential, except as otherwise noted.

C. Conflict of interest disclosure

Suppliers bidding on PATH business must disclose, to the procurement contact listed in the RFP, any actual or potential conflicts of interest. Conflicts of interest could be present if there is a personal relationship with a PATH staff member that constitutes a significant financial interest, board memberships, other employment, and ownership or rights in intellectual property that may be in conflict with the supplier's obligations to PATH. Suppliers and PATH are protected when actual or perceived conflicts of interest are disclosed. When necessary, PATH will create a management plan that provides mitigation of potential risks presented by the disclosed conflict of interest

D. Communication

All communications regarding this solicitation shall be directed to appropriate parties at PATH indicated in Section XI. A. Contacting third parties involved in the project, the review panel, or any other party may be considered a conflict of interest and could result in disqualification of the bid.

E. Acceptance

Acceptance of a proposal does not imply acceptance of its terms and conditions. PATH reserves the option to negotiate on the final terms and conditions. We additionally reserve the right to negotiate the substance of the finalists' bid, as well as the option of accepting partial components of a proposal if appropriate.

F. Right to final negotiations

PATH reserves the option to negotiate on the final costs and final scope of work, and also reserves the option to limit or include third parties at PATH's sole and full discretion in such negotiations.

G. Third-party limitations

PATH does not represent, warrant, or act as an agent for any third party as a result of this solicitation. This solicitation does not authorize any third party to bind or commit PATH in any way without our express written consent.

H. Proposal Validity



Proposal submitted under this request shall be valid for 60 days from the date the date the proposal submission is due. The validity period shall be stated in the proposal submitted to PATH.



RFP# 2021-069: Annexure A – Letter of Proposal

To,

PATH
15th Floor, Dr. Gopal Das Bhawan,
28 Barakhamba Road
New Delhi 110001

Subject: RFP# 2021-069: Proposal for Consultancy Services to assist Five Laboratories in Private Sector in obtaining NABL Accreditation for Assay (Purity) of Medical Grade Oxygen as per ISO/IEC 17025:2017

Dear Sir,

1. Having examined the RFP documents and appendix thereto, we, the undersigned, in conformity with the said document, offer to execute the services as given in the Scope of Services – Annexure E, with the RFP documents
2. We undertake, if our proposal is accepted, to execute the works within time frame specified, starting from the date of receipt of issue of Work Order (WO) from PATH.
3. We agree to execute a WO in the form to be communicated by PATH, incorporating all agreements with such alterations or additions thereto as may be necessary to adapt such agreement to the circumstances of the standard and notice of the award within time prescribed after notification of your intention to accept this proposal.
4. We would like to clearly state that we qualify for this work as we meet all the eligibility requirements indicated by you in the RFP Documents.
5. We certify that all the information mentioned in Particulars of Consultant - Annexure B of this covering letter is true and correct.
6. We understand that if the details given in support of claims made above are found to be untenable and/or unverifiable our proposal may be rejected without any reference to us. We further clearly understand that PATH is not obliged to inform us of the reasons of rejection of our proposal.
7. It is certified that the information furnished herein and as per the document submitted is true and correct and nothing has been concealed or tampered with. We have gone through all the conditions of RFP and are liable to any punitive action for furnishing false information/documents.

Dated this ____ day of 20__



Signature
(Consultant's Seal)

In the capacity of
Duly authorized to sign proposal for and on behalf of:

RFP# 2021-069: Annexure B - Particulars of Consultant

1. Name of the Consultant: _____
2. Address of the Consultant: _____
 _____ District _____ PIN _____
3. Email Address: _____
4. Phone: _____
5. Incorporated as: _____ in year _____ at _____ (Company, State Registered Firm, Co-operative Society or Partnership Firm)
6. Whether any legal arbitration/proceeding is instituted against the consultant or the consultant has lodged any claim in connection with works carried out by them (Yes/No): _____
7. If yes, please give details. _____
8. Whether the Consultant complies with the requirement of Registration under the Contract Labour (Regulation and Abolition) Act (Yes/No): _____
9. **Consultant's profile:**
 - a. Name of the top executive: _____
 - b. Designation: _____
 - c. Email Address: _____
 - d. Mobile Number: _____

10. Number of Experts available with the Consultant:

Sl. No.	Name of Expert	Nature of engagement (Full Time / Part Time / Need Based)	Qualification	Experience

11. Experience of providing consultancy services for NABL Accreditation.

A. Name of Clients (Laboratories) who have received NABL Accreditation through the Consultant in last five years (as on the due date for submission of proposals:

Sl. No.	Name and address of Client (Laboratory)	NABL Certificate Number	Date of award of NABL Certificate	Scope of Accreditation

B. Name of Clients (laboratories) to whom the firm is in process of providing consultancy for acquiring NABL Accreditation:

Sl. No.	Name and address of Client (Laboratory)	Date of appointment of Consultant	Scope of Accreditation	Time frame as per work order / consultancy contract

Note: Please submit copy of Contracts / Work Orders as stated in the table above.

12. **Consultant's Annual Turnover (In Rs.)**

Financial Year	Annual Turnover (Rs.)
2018-19	
2019-20	
2020-21	

Note: Please submit Certificate of Annual Turnover issued by statutory auditor / chartered accountant and audited balance sheets



Documents in support of the above may be furnished with page numbers indicated in the index. Please use separate sheets wherever necessary.

Date

Place

Consultant's Seal



RFP# 2021-069: Annexure C – Approach, Methodology and Work Plan

*[Consultants are required to submit their approach, methodology and work plan to execute the works as per Scope of Services – Annexure-E, **not more than 10 pages**. This should include list of manpower / experts to be deployed along with their brief profiles. The work plan should be in form of Gantt Chart giving all activities and their timelines as against the timelines given in Scope of Services.]*

RFP# 2021-069: Annexure D – Financial Proposal

Brief Description of Services	Qty (No. of labs)	Unit Rate (exclusive of GST) (INR)	GS T Rate	GST Amount	Total Unit Price (inclusive of GST) (in figures)	Total Price (in figures)	Total Price (in words)
A	B	C	D	E	F = C+E	G = B x F	H
Consultancy Services to assist Laboratories in Private Sector in obtaining NABL Accreditation for Assay (Purity) of Medical Grade Oxygen as per ISO/IEC 17025:2017 (as per Scope of Services – Annexure E)	5						

- The rates quoted should be as per industry standards. Proposals quoting zero or abnormally low rates compared to the industry prevalent rates will be rejected.
- The rates finalized will not be changed throughout the period of proposal validity.
- The consultant may be awarded works for performance of services at additional labs, at the rate quoted above. For such laboratories, the NABL's Application fee and other expenses towards of NABL's Assessors may be directly paid to by the respective laboratories.

Name of Supplier:

Authorized Signatory:



Name

Date

Place

Consultant's Seal

Scope of Services for

Consultancy Services to assist Five Laboratories in Private Sector in obtaining NABL Accreditation for Assay (Purity) of Medical Grade Oxygen as per ISO/IEC 17025:2017

A. Introduction:

PATH is supporting five Laboratories in the Private Sector in obtaining NABL Accreditation for Assay (Purity) of Medical Grade Oxygen as per ISO/IEC 17025:2017. These laboratories shall be among such laboratories who are already carrying out oxygen purity testing, but could not get NABL Accreditation so far. These five laboratories shall be one each from Odisha, Maharashtra, Rajasthan, Madhya Pradesh and Punjab. PATH may add more laboratories for extending support under the RFP. However, these additional laboratories shall be requested to deposit Application Fee directly to NABL and also bear other expenses such as travel expenses, honorarium, boarding and lodging expenses of NABL's Assessors per NABL's rules / policies.

B. Scope of Services:

The consultant shall be responsible for execution of following services for each of the five Laboratories:

- 1) The Consultant shall conduct Gap Assessment of the five Laboratories proposed by the PATH for preparedness and assess for their qualification to conduct Assay (Purity) of Medical Grade Oxygen as per NABL Accreditation requirements. The Consultant shall suggest infrastructure changes required, if any; calibration requirements, and document system design requirements.
- 2) The Consultant shall review the existing laboratory quality management system in compliance with ISO 17025:2017 standards as required for the NABL accreditation and suggest improvements, if any; The Consultant shall assist in revising Quality Manual / Standard Operating Procedures (SOPs) / Documentation such as adopted test methods, reporting of test results, Internal Quality Control, Test Data Verification, Validation and Maintenance of Records for testing, etc.
- 3) The Consultant shall conduct two day awareness training on the requirements of the ISO/IEC 17025:2017 and NABL specific requirements at each of the five laboratories. This shall cover at the minimum documentation, implementation, quality control, pre-analytical errors and document control. The training shall be in the form of workshop to generate awareness of ISO /IEC 17025:2017 for lab staff. It would also help them fulfil their roles as members of steering committee in monitoring overall process of system development, implementation and

to enable them steer the process of system development and implementation in line with NABL requirement.

- 4) The Consultant shall conduct one-day training on verification of measurements / uncertainty of measurements to Lab staff as per requirement of NABL testing.
- 5) The Consultant shall conduct oneday training on internal audit based on ISO/IEC 17025:2017 at each of the five laboratories. The training shall cover topics such as audit objectives, audit methodology and reporting systems as per ISO/IEC 17025:2017. In addition, on-the-job audit activity exercises shall be carried out so that auditors are fully familiar with the techniques of auditing.
- 6) The Consultant shall assist in preparing Traceability, Calibration, Accuracy, Uncertainties, Measurement Capabilities of Instruments / Equipment used in Laboratories for Assay (Purity) of Medical Grade Oxygen.
- 7) The Consultant shall conduct Internal Audit and mock assessment to review preparedness of the laboratory for assessment by NABL. The consultant shall assist in Non Conformity closure raised during internal audit / mock assessment.
- 8) The Consultant shall identify the legal requirements if any, related to the analysis and certification.
- 9) The Consultant shall assist for submitting application for NABL Accreditation. The Consultant shall examine, review and confirm the final documentation as required for NABL certification.
- 10) The Consultant shall be present during during pre-assessment and final assessment by NABL and guide / assist for taking necessary corrective actions in closing the observations on the concerns raised during the assessments, if any.
- 11) The Consultant shall assist in submission of corrective actions to NABL, if any.
- 12) The Consultant should make available offline as well as online support for queries related to NABL till Certification.
- 13) The consultant shall ensure the laboratory get a NABL accreditation without any major or minor non-conformance.

C. Support to be provided by PATH:

- a) PATH shall depute a nodal person for coordination between selected Consultant and Laboratories during execution of services.
- b) PATH shall bear all the cost associated with NABL Accreditation, such as Application Fee, Annual Accreditation Fee for 1 year, Assessment charges, and Honorarium for NABL Assessors and travel, boarding and lodging expenditure for Assessors as recommended by NABL.

D. Timelines for key Deliverables:

The suggestive timelines for completion of key deliverables are as under:

Sl. No.	Brief Description of key Activity	Deliverables	Timeline (No. of days)
1	Completion of Gap Assessment of the five Laboratories	Gap Assessment Report of five Laboratories	20 days
2	Completion of review of existing Quality Manuals, SOPs, Forms, etc. and revisions thereof and completion of all scheduled trainings	Revised Quality Manuals, SOPs, Forms and Training Reports	20 days
3	Internal Audit and mock assessment and closure on non-conformities noted during Internal Audit and mock assessment	Report on preparedness for submission of Application to NABL	30 days
4	Application submission to NABL, pre-assessment completed by NABL's assessors, necessary corrective actions taken in closing the observations, if any	Pre assessment report and corrective actions submitted to NABL	20 days
5	NABL Certificate issued to all five laboratories	NABL Certificates	30 days
	TOTAL		120 days