



United Accreditation Body of India

Application Form for Reference Material Producers



AMENDMENT SHEET

S.No	Page No.	Clause No.	Date of Amendment	Amendment	Reasons	Signature QM	Signature CEO
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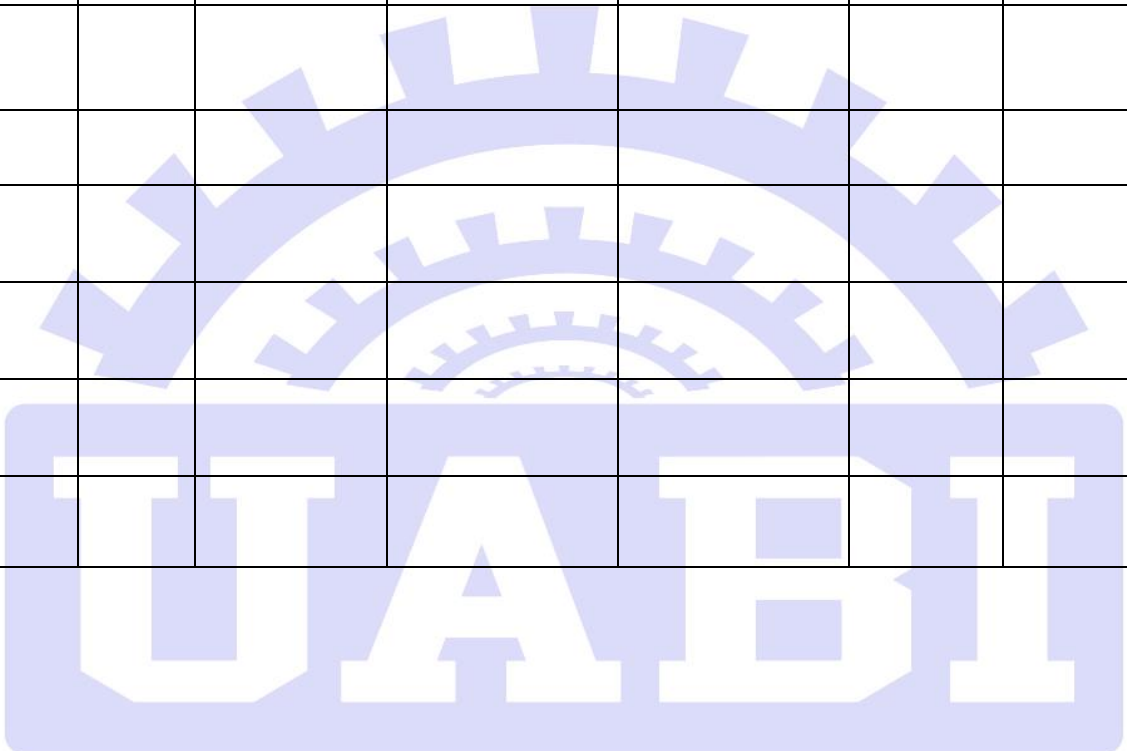
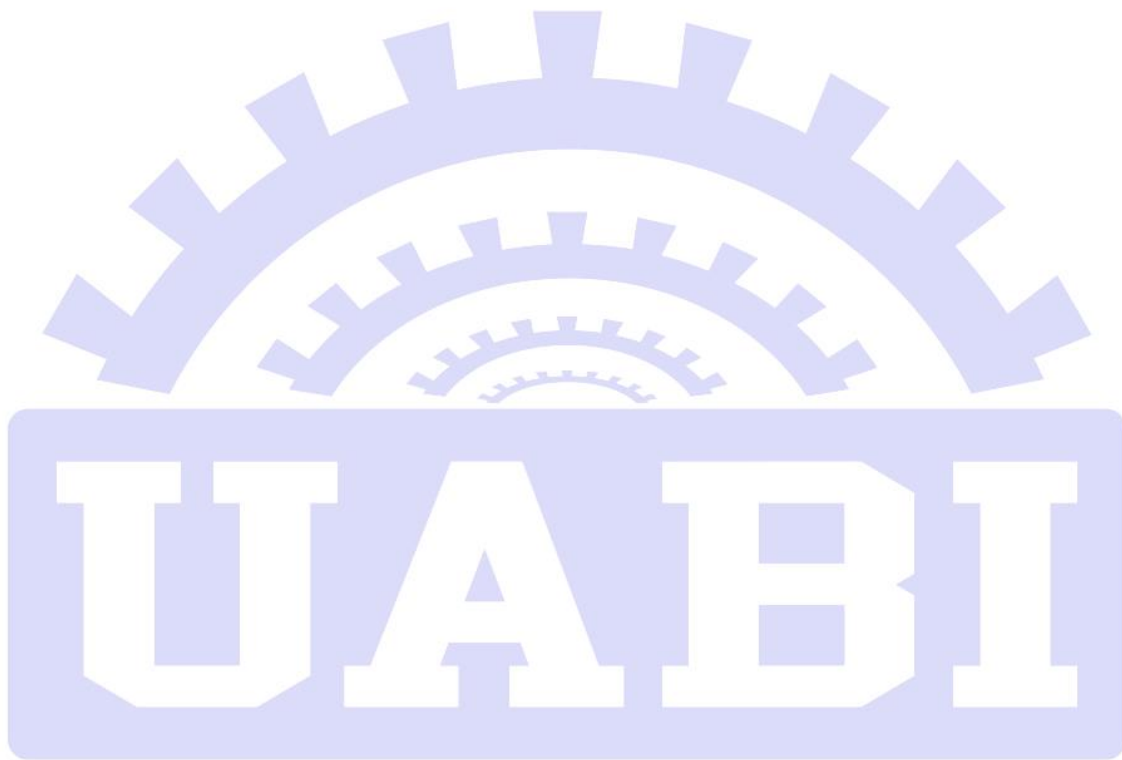


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Application Form for CAB Accreditation

Accreditation Type (First/Renewal/Scope Extension/Surveillance audit):

Previous accreditation details along with certificate no. & validity _____

1. CAB Details

Name of the Organization

Details about CAB Location(s) and Address(s) other locations also if applicable any:

Contact Details (Such as phone number, mail I'd etc.): _____

1.1. Category of Facility(s) applied under the scope of Accreditation

- | | | |
|-----------------------|------------------------------|-----------------------------|
| a. Permanent Facility | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| b. Site Facility | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| c. Mobile Facility | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

1.2. Name of Organization / Parent Organization along with contact details:

1.3. Legal identity of the CAB and date of establishment

(Please give Registration No. and name of issuing authority. Attach supporting evidence)

1.4. Government TAX registration Number such as GST and TAN/PAN or others if applicable: -

1.5. Type of scope of Accreditation:

(Please tick appropriately)

- Reference Material Producer
- Certified Reference Material Producer

1.6. How Reference Material Producer activities are conducted

(Please tick appropriately)

- At Permanent Facility
- Mobile or Temporary Facility

Note: UABI does not accept application if reference material producer sub-contracts any of its activity.

Kindly mention other Accreditations granted such as but not limited to ISO 17025, ISO 9001, ISO 14001 etc.

1.7. Mention how the name along with address of the CAB that are to appear on the certificate

(In English or other language as applicable)

2. Accreditation Details as per relevant Scope:

2.1. Categories for which accreditation is sought (For reference, kindly see Annexure-1)

- Physical properties
- Engineering properties
- Chemical composition
- Biological and clinical properties
- Miscellaneous (treated as another category not mentioned above)

2.2. Format for Scope of Accreditation

S. No.	Type of Reference materials (certified reference material or reference material)	Reference material matrix or Source used	Property of reference material	Test method used or any validated method used to assign property value	Range of Testing/ Limits of detection	Uncertainty of Measurement (\pm) at Value

Note:

- i. CAB shall apply scope as per format only and no other format is accepted by UABI.
- ii. Measurement of Uncertainty shall be expressed at with 95% of confidence level

Organization Structure

2.3. Senior Management

2.3.1. Top management of the CAB _____

2.3.2. Person responsible for the management system (Quality Manager as said) _____

2.3.3. Person responsible for technical operations (Technical Manager as said) _____

2.3.4. Contact person for UABI _____

2.4. Proposed personnel that are competent for Signing of reference material certified reports as well as for authentication of test data. Fill in this format only.

(Please note to attach RMP's qualification and experience criteria along with this form)

Sl.	Department/Section	Name & Designation	Qualification with Specialization	Relevant Experience in years for Authorized signatory	Relevant Training	Specialization for authorized signatory	Specimen Signature

2.5. Organization Chart details:

2.5.1. Indicate how organization chart for operating departments of the CAB for which accreditation is being sought. (Attach sheet separately)

2.5.2. Indicate how the CAB is related to external organizations or to its own parent organization (if applicable)

2.6. Employees details, (Fill in this format only).

2.6.1. Details of staff

S.No	Name	Designation	Academic and Professional Qualifications	Experience related to present work (in years)	Relevant Training

Note:

- i. CAB operating in shifts shall clearly identify the staff working in shifts.

3. Equipment and Reference Materials/ Reference standards

3.1. List of equipment, (Fill in this format only).

Sl.	Name of equipment	Model/ type/ year of make	Range and accuracy	Date of last calibration	Calibration due on	Calibrated by*	Traceability

* Please mention whether calibration done in-house or through external agency (mention name).

4.2 List of Reference Standard available for use, (Fill in this format only).

S.No	Name of Reference Material / Standard strain / Culture used	Source / Name of manufacturer	Date of Validity	Traceability

4. Internal Audit and Management Review details:

4.1. Dates of last Internal Audit _____

4.1.1. Whether all requirements of ISO/IEC 17034:2016 covering all activities of CAB have been audited at least once in last one year

YES/NO (Mark Appropriately)

4.2. Dates of last Management Review _____

5. Application Fees details:

1.1. Number of groups* applied for accreditation _____

1.2. Application Fees (Rs.) _____

1.3. **DD/ Online Mode (Mention reference no.) (Please refer UABI 449) _____

Note:

- i. *Information regarding the groups applied for accreditation in each discipline. Refer UABI 412 for more details.
- ii. **All payments shall be made through DD/RTGS/NEFT & should be in favor of 'UABI' payable at DELHI.
- iii. CAB can make separate Annexures for filling details given in point 2.2 to 4.2.

6. Declaration by the CAB

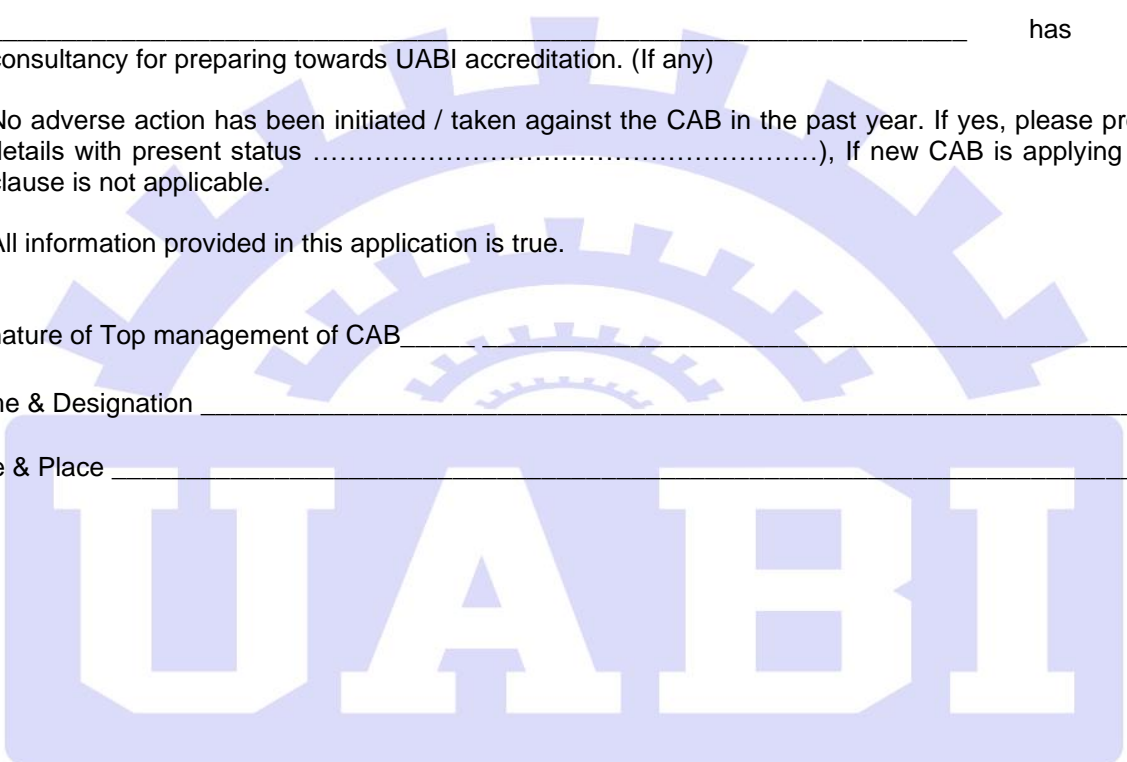
We declare that

- 8.1 We are familiar with the terms and conditions of maintaining accreditation (UABI 417), which is enclosed and will abide by them at all time during period of accreditation.
- 8.2 We agree to comply fully with ISO/IEC 17034: 2016 for the accreditation during all time on & for accreditation.
- 8.3 We agree to comply with accreditation procedures and pay all costs for any kind assessment at all time.
- 8.4 We agree to co-operate with the assessment team appointed by UABI for assessment and as per applied scope.
- 8.5 We satisfy all national, regional and local regulatory requirements for operating a CAB.
- 8.6 _____ has provided consultancy for preparing towards UABI accreditation. (If any)
- 8.7 No adverse action has been initiated / taken against the CAB in the past year. If yes, please provide the details with present status _____), If new CAB is applying then this clause is not applicable.
- 8.8 All information provided in this application is true.

Signature of Top management of CAB _____

Name & Designation _____

Date & Place _____



7. Application Form Check List, please mark as appropriately.

S. No	Information / details provided as part of application	Check mark
1.	Information about each discipline (as per Annexure – 1)	
2.	Management System Document / Quality Manual (latest issue) according to latest ISO/IEC 17034: 2016.	
3.	Application fees a) Information on total groups applied for accreditation b) Estimated applicable fees as per UABI 449. c) Demand Draft in favor of 'UABI' & details of NEFT/RTGS.	
4.	Copy of Legal Identity (Registration Details of the CAB)	
5.	Government registration TAX number along with details (GST, PAN etc.)	
6.	Scope of Accreditation along with all necessary details as per Scope format.	
7.	Details of Senior Management along with designation and Contact Details	
8.	List of staff and signing authority of CAB	
9.	Organization Chart	
10.	List of Equipment's / Reference Material used with details of Traceability	
11.	Documentation for, planning of production processes, homogeneity & stability testing and storage, handling and distribution of reference material.	
12.	Dates of last Internal Audit and Management Review.	
13.	Declaration about the Consultant (if any)	
14.	Signed copy of UABI Terms & Condition.	

Verified the above details and confirmed the availability of all required documents/ details as part of application form.

Signature of CAB/ QA Head / Director _____

Name & Designation _____

Date & Place _____

UABI 417

Terms & Conditions for Obtaining and Maintaining UABI Accreditation

(To be submitted to UABI along with the application form)

The Conformity Assessment Bodies which is Testing including Medical / Calibration Laboratories that are applicant / accredited by UABI shall be required to fulfill the following terms and conditions:

1. The Conformity Assessment Bodies (CABs) that carry out its testing / calibration / medical activities in such a way as to meet the requirements of ISO/IEC 17034 relevant UABI specific criteria (wherever applicable) and other policies of UABI.
2. The CAB shall have a valid legal identity.
3. The CAB shall meet the requirements of UABI and as per ISO 17034:2016
4. The CAB shall identify and define various activities which they are involved in, and make sure it does not lead to any potential conflict of interest and does not affect test data results.
5. The CAB shall have adequate qualified and trained manpower for the stated scope and for authenticity and issue of COA (Certificate of Analysis) reports and for review, evaluation & release of results, as applicable who meets the requirements of relevant UABI criteria for each field / discipline of accreditation.
6. The designated Quality Manager / management system documentation person, responsible for implementation, maintenance and improvement of the management system, shall have successfully underwent training for ISO/IEC 17034 from a reputed training institute.

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Doc No. UABI 417	Doc Name: Terms & conditions for maintaining & obtaining accreditation	
Issue No. 1	Issue Date: 02.04.2021	Issued By QM:
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7. CAB has to submit application for renewal of accreditation three months prior to the expiry of accreditation and also agree to undergo assessment as per UABI to maintain continuity in their accreditation cycle.
8. The CAB shall offer cooperation to UABI or its representative in:
 - a. Assessments as per stipulated time intervals / whenever it is as required.
 - b. Access to all specific areas of operations.
 - c. Undertaking for check / inspection to verify the capability of the CAB for the applied scope.
 - d. Witnessing the activities as per scope of accreditation.
 - e. Assessing the competence of the staff (including staff working in shift operations / at site) during assessment.
 - f. Access to all areas for information, documentation as well as for records pertaining to staff members
 - g. Access to those documents that provide insight into the level of independence and impartiality to the CAB from its related bodies, if applicable.
 - h. Providing names of all authorized signatory (s) who are responsible for authenticity, issue of test / calibration reports as well as for review, evaluation & release of results.
 - i. Investigating any complaints/feedback against the CAB during accreditation cycle plus along with previous accreditation cycle.
9. On grant of accreditation, the CAB shall claim accreditation in only those premises, fields, facilities, disciplines, for which it has been accredited (as stated in Accreditation Certificate).
10. CAB applying for accreditation shall comply with the requirements of standard as well as UABI's Policies for Accreditation as per ISO/IEC 17034:2016 applicable.
11. Accredited CAB shall make it clear in all its contracts with customers that its activities falling under accredited scope in no way imply that the product so tested or equipment calibrated is approved by UABI.
12. CAB shall make sure that in no way it implies to the process system or person that is approved by UABI.

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13. The CAB has to pay applicable application & accreditation fee as per UABI 449.
14. The CAB shall inform UABI of any significant changes affecting the CAB's activities and operations relevant to accreditation to UABI within 10 days, such as:
 - a. its legal, commercial, ownership or organizational status
 - b. the organization, top management and key personnel including authorized signatories
 - c. main policies
 - d. resources and premises
 - e. other such matter that may affect the ability of the CAB to fulfill the requirements of ISO/IEC 17025.
 - f. any change in the Sample Collection Centre/ Facility (ies) to UABI.
15. The CAB has to make sure of itself that they have updated documents with them of UABI and all other relevant standard as applicable at all time.
16. The CAB shall unambiguously declare the name of any individual or organization that has provided consultancy for preparing towards UABI accreditation.
17. The accredited CAB shall itself normally perform the activities which is covered under scope of accreditation. Where a CAB subcontracts a substantial or critical part of the accredited activities that work shall be placed with another accredited CAB only.
18. The accredited CAB shall respond promptly to the changes initiated by UABI in its accreditation criteria, policies and procedures. The CAB shall inform UABI when such alterations under the agreed time frame have been completed.
19. CAB shall take corrective actions to close all the non conformities raised during the assessment within 30 days time to avoid any disciplinary action as per UABI 420
20. CAB shall not involve itself in any kind of malpractices or fraudulent which may bring UABI to disrepute.
21. The accredited CAB upon suspension or withdrawal of its accreditation (however determined) or expiry of validity of accreditation shall forthwith discontinue its use of all advertising matter that contain any reference to the accreditation status and shall return the certificates of accreditation to UABI within 15 days of timeframe.

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22. The accredited CAB can withdraw accreditation by giving notice in writing to UABI by surrendering the certificates of accreditation within 15 days of timeframe after notice.

23. The CAB shall inform UABI, if any of the proposed assessor(s) happens to be their Consultant or associated with the CAB in any other capacity.

By signing this document, it is implied that a **CAB or laboratory as said** as an applicant and after obtaining accreditation agrees to comply at all times with **Terms and Conditions of UABI. Any violation of this terms and conditions shall result in adverse decision as per UABI 442.**

Signature of Top management:

Name & Designation of Top management:

CAB Name:

Date & Place:

Signature of UABI Official & Date of Receipt (For office use only):

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ANNEXURE – 1

Categories for which accreditation is sought by Reference material producer (RMP).

- **Category A** (Chemical Composition)
 1. Ferrous Materials
 2. Non-ferrous Materials
 3. Organic reference material
 4. In-organic reference material
 5. Environmental and gases reference material

- **Category B** (Biological and Clinical Properties)
 1. General Medicine
 2. Bacteriology and Mycology
 3. Clinical Chemistry
 4. Other Biological and Clinical reference Material

- **Category C** (Physical Properties)
 1. Electrical Properties
 2. Magnetic Properties
 3. Thermodynamic Properties
 4. Physiochemical Properties

- **Category D** (Engineering Properties)
 1. Ferrous Material (i.e., Hardness, impact etc.)
 2. Reference Bar (i.e., for Non-Destructive Testing)
 3. Anvil (i.e., for Non-Destructive Testing)
 4. Surface finishing
 5. Sizing chart