1. Details from the CAB:

|  |  |
| --- | --- |
| **Name**  |  |
| **Address** |  |
| **Authorized Representative:** |  | **ENAS ID:** |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Type of assessment:** | Choose an item. | **Date(s) of assessment:** |  |
| **Assessment Technique:** | Choose an item. |

|  |  |
| --- | --- |
| [ ]  Testing laboratory [ ]  Calibration laboratory | CAB with several locations: [ ]  Yes [ ]  No |
| Assessed locations: | Name and Address: |  |
| Name and Address: |  |
| Name and Address: |  |
| 1. **Details of the Assessment Team:**
 |
| Lead Assessor: |  | Quality Assessor(s): |  |
| Technical Assessor(s): |  |
| Technical Expert(s): |  | Observers or others: |  |

1. **Nonconformity codes used in this report:**

**Accreditation requirements include the relevant standard and any relevant ENAS additional requirements**

|  |
| --- |
| **ENAS Findings Categories** |
| **Category**  | **Definition** | **Closue of Findings**  |
| **Nonconformity (NC)** | A finding that identifies nonconformity is indicated as ‘NC’ (Non Conformity) in the NCR sheet and in the Assessment Report. It indicates a failure to meet accreditation criteria [e.g. Accreditation Standard, ILAC, ENAS requirements, MS requirements ...] that leads to non valid activity results and/ or threatenes the integrity of the Accreditation Body, and/ or leads to non-effectiveness of CAB management system. | The CAB shall take appropriate action to resolve the nonconformity prior to ENAS granting or confirming continuity of accreditation. Response on action taken is required with supporting evidence against each findings indicated as ‘NC’ with evidencse provided in the time that has been negotiated for response. |
| **Observation (O)** | A finding that identifies an opportunity for improvement or a weakness that may lead to a nonconformity if not considered (potential nonconformity) | This may be a recommendation or a reminder or flag for follow-up/review at the next assessment. |

# Status of conformity to accreditation requirements including document review

| **Ref. clause** | **Element /Chapter** | **Compliant** | **Not****Compliant** | **Not Applicable** | **Procedure/Sample records checked** | **Comments:****Reason(s) for not complying, Good practices, opportunities for improvement, ref. to finding number from NC sheet** |
| --- | --- | --- | --- | --- | --- | --- |
| 4.1 | Impartiality | [x]  | [ ]  | [ ]  |  |  |
| 4.2 | Confidentiality | [ ]  | [x]  | [ ]  |  |  |
| 5 | Structural requirements | [ ]  | [ ]  | [x]  |  |  |
| 6.2 | Personnel | [ ]  | [ ]  | [ ]  |  |  |
| 6.3 | Facilities and environmental conditions | [ ]  | [ ]  | [ ]  |  |  |
| 6.4 | Equipment | [ ]  | [ ]  | [ ]  |  |  |
| 6.5 | Metrological traceability | [ ]  | [ ]  | [ ]  |  |  |
| 6.6 | Externally provided products and services | [ ]  | [ ]  | [ ]  |  |  |
| 7.1 | Review of requests, tenders and contracts | [ ]  | [ ]  | [ ]  |  |  |
| 7.2 | Selection, verification and validation of methods | [ ]  | [ ]  | [ ]  |  |  |
| 7.2.1 | Selection and verification of methods | [ ]  | [ ]  | [ ]  |  |  |
| 7.2.2 | Validation of methods | [ ]  | [ ]  | [ ]  |  |  |
| 7.3 | Sampling | [ ]  | [ ]  | [ ]  |  |  |
| 7.4 | Handling of test or calibration items | [ ]  | [ ]  | [ ]  |  |  |
| 7.5 | Technical records | [ ]  | [ ]  | [ ]  |  |  |
| 7.6 | Evaluation of measurement uncertainty | [ ]  | [ ]  | [ ]  |  |  |
| 7.7 | Ensuring the validity of results | [ ]  | [ ]  | [ ]  |  |  |
| 7.8 | Reporting of resultsGeneralCommon requirements for reports (test, calibration or sampling)Specific requirements for test reportsSpecific requirements for calibration certificatesReporting sampling – specific requirementsReporting statements of conformityReporting opinions and interpretationsAmendments to reports | [ ]  | [ ]  | [ ]  |  |  |
| 7.9 | Complaints | [ ]  | [ ]  | [ ]  |  |  |
| 7.10 | Nonconforming work | [ ]  | [ ]  | [ ]  |  |  |
| 7.11 | Control of data and information management | [ ]  | [ ]  | [ ]  |  |  |
| 8 | Management system requirementsOption AOption B | [ ]  | [ ]  | [ ]  |  |  |
| 8.2 | Management system documentation (Option A) | [ ]  | [ ]  | [ ]  |  |  |
| 8.3 | Control of management system documents (Option A) | [ ]  | [ ]  | [ ]  |  |  |
| 8.4 | Control of records (Option A) | [ ]  | [ ]  | [ ]  |  |  |
| 8.5 | Actions to address risks and opportunities (Option A) | [ ]  | [ ]  | [ ]  |  |  |
| 8.6 | Improvement (Option A) | [ ]  | [ ]  | [ ]  |  |  |
| 8.7 | Corrective actions (Option A) | [ ]  | [ ]  | [ ]  |  |  |
| 8.8 | Internal audits (Option A) | [ ]  | [ ]  | [ ]  |  |  |
| 8.9 | Management reviews (Option A) | [ ]  | [ ]  | [ ]  |  |  |

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| **If the laboratory has adopted Option B*****Where the following cannot be confirmed, then assessment of the laboratory’s management system shall be against Option A requirements.*** ***Where nonconformities are identified, these are to be raised against clause 8.1.3.*** |
| * Is the management system is certified by a certification body (CB) accredited by ENAS or Accreditation Body signatory to the International Accreditation Forum (IAF) Multilateral Recognition Agreement (MLA).
 |  |  |  |  |  |
| * Evidence that the CB’s accreditation covers ISO/IEC17021-3 i.e. the CB can certify management systems to ISO 9001.
 |  |  |  |  |  |
| * Most recent audit report(s) issued by the Certtification Body covering the laboratory’s Management system in full.
 |  |  |  |  |  |
| * Evidence on the closure of nonconformities raised during certification audits.
 |  |  |  |  |  |
| * Evidence that certification of the management system includes the laboratory activities covered by its ENAS scope of accreditation.
 |  |  |  |  |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Element /Chapter** | **Compliant** | **Not****Compliant** | **Not Applicable** | **Procedure/Sample records checked** | **Comments:****Reason(s) for not complying, Good practices, opportunities for improvement, ref. to finding number from NC sheet** |
| Use of the ENAS Accredited Symbol (EP02) | [ ]  | [ ]  | [ ]  |  |  |
| ENAS Technical Requirements on Participation in proficiency Testing  | [ ]  | [ ]  | [ ]  |  |  |
| ENAS Technical Requirements on Metrological Traceability and Measurement Uncertainty | [x]  | [ ]  | [ ]  |  |  |
| ENAS Technical Requirements on Measurement Uncertainty | [x]  | [ ]  | [ ]  |  |  |
| ENAS other Technical Requirements (whenever applicable) | [x]  | [ ]  | [ ]  |  |  |
| Fulfilment of imposed conditions, implementation of the corrective actions from the previous assessment | [ ]  | [ ]  | [ ]  |  |  |

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| **Comments and Recommendation of the Technical Assessor(s) / Expert(s)** |
| Name TA / TE:  |  |
| Name: TA / TE: |  |
| Name: TA / TE: |  |
| **Summary report by Assessment Team via Lead Assessor** |
| Other Existing accreditations and certifications (if any) |  |
| Strengths of the CAB’s management system |  |
| Weaknesses of the CAB’s management system  |  |
| Competence of the personnel responsible for implementation of management system. |  |
| Areas for improvement (if any) |  |
| overall impression with respect to laboratory’s compliance with the requirements of accreditation including that of ENAS’s requirements. |  |
| Any other comments |  |

1. Method Review Matrix

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Name of ENAS Assessor (TA/TE)** | **Parameter/****Test Name or****Technology** | **Depth of****Assessment****\*see codes** | **Name(s) of****Personnel****interviewed** | **Standards/****Equipment/****Ref. Materials** | **Procedure/****Operating****Instructions** | **Measurement****Uncertainty****Verification** | **Traceability;****Verification/****Calibration** | **Sampling;****Handling/****Preparation** | **Quality****Checks** | **Records****Report/****Certificate** | **Comptence of personnel (witnessed, interviewed)** |
|  |  |  |  |  |  |  |  |  |  |  |  |
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***Note:*** *Insert as many rows as required in the above table to enlist whole of the scope covered.*

 **\*O = Observed Test; R = Remotely Observed/ interviewed ; P = Procedure Reviewed; I = Interviewed Personnel; E = Equipment Inspected; F = Field (On-Site); NR = Not Running**

Please complete table for each parameter/test/technology and the corresponding method(s) in the following categories:

* Parameter, Test Name or Technology: For calibration labs, list parameter and tool (dimensional-calipers, force, etc.); For testing labs list Test category and name (Chemical, Biological, etc.) and GC-MS or Salmonella
* Depth of Assessment: Record the extent to which the parameter/test was assessed as follows:
	+ O = Observed Calibration or Test
	+ R = Remotely Observed Calibration or Test
	+ I = Interviewed Person(nel)
	+ P = Procedure Reviewed
	+ E = Equipment Inspected
	+ F = Field (On-Site) Calibration and/or Test

You may have a combination of the above (e.g. O/I/P, R/I/P, I/P, I/E, O/I/E/F) **You must verify, at a minimum, that the laboratory has the equipment, method, and trained personnel to perform each calibration/test on the proposed Scope of Accreditation.**

* Personnel Interviewed: List name(s) of personnel with prospective competence for the method.
* Environmental Conditions,: Indicate whether the environment/facility/equipment was suitable for the methods listed, and any environmental monitoring devices (which may also require traceability)..
* Standards/Equipment//Reference Materials: all reference standards and equipment utilized, trying to list all those mentioned on the proposed scope of accreditation,
* Procedure/Operating Instructions: Indicate the specific laboratory internal procedures or instructions for performing the calibration or test, and whether they were acceptable. Be sure to note the same methods as noted on the proposed scope of accreditation.
* Measurement Uncertainty: Indicate whether uncertainty analysis is required for the method; if required, indicate if laboratory analysis is acceptable. May indicate to be verified later (TBV)
* Verification/Calibration: Indicate whether the calibration or verification data for the relevant equipment is acceptable, and any objective evidence observed.
* Sampling; Handling/Preparation of Items: Indicate all protective gear used for the methods, whether the laboratory performs any sampling for the listed methods, and indicate if those activities, as well as any handling or preparation performed, are acceptable.
* Quality Checks: Indicate what quality checks are in place and whether they are acceptable.
* Records: Indicate whether the appropriate records are maintained for the listed methods, and what records were reviewed. Note all hand-written. Logbooks, or forms utilized. Many may have differing record retention times.

Report/Certificate: Indicate whether the results for the listed methods are appropriately reported in accordance with 17025 and any requirements of the methods. Note if reports issue out of a database, electronic or templates.

1. **List of Authorized Signatories on Test Reports**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **#** | **Name** | **Position** | **Authorization Date** | **Scope of Authorization** |
|  |  |  |  |  |
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1. **Final report recommendations**

|  |  |
| --- | --- |
| **Recommendation to grant accreditation (please tick):** |  [ ]  Granted/renewed [ ]  Maintained [ ]  Reduced [ ]  Extended [ ]  Not granted/not renewed  [ ]  Suspended (Partial) [ ]  Suspended (Full)  |
| **Next assessment is recommended within:**  |  |
| **Additional information if any changes in the scope(s) (suspension, reduction or extension):** |  |
| **Any special conditions/Remarks attached to the recommendations:** |  |
| **Name**  |  | **Date:** |  |
| **Signed on behalf of assessment team:** |  | **Updated on & By/ Signature :** |  |

1. **Recommended scope of Accreditation [See attached, Accreditation Scope - ACF 11-22]**

[Lead Assessor to ensure that Assessment Team has completed/reviewed the ENAS Accreditation scope document (ACF 11-22) in their respective fields. It is agreed by the CAB and is attached along with this report]

1. **Attendance**

|  |  |
| --- | --- |
| **Opening meeting** | **Closing meeting** |
| **Name**  | **Position** | **Name**  | **Position** |
| **Assessment Team Members** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| **Participants from the CAB** |
|  |  |  |  |
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**Note:** *Names of those members of the assessment team, who attended the above meetings, shall be recorded*. N*ames of the key staffs are required for CAB’s participants. There is no requirement of signature for this attendance.*