**Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Ref.:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Assessor name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Assessor status:** [ ]  **Lead assessor,** [ ]  **Profeesional Assessor**

**OBSERVATION NOTEBOOK**

# All notes should be written with a blue pen

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| **ISRAC Lab. no:** |  |
| **Name of organization:** |  |
| **Organization representative name:** |  |
| **Site type:** |  |
| **Assessment dates:** |  |
| **Extension requested:** |  |

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| **Observation Notebook submitted**  | [ ]  **By paper** [ ]  **By Electronic file**  |

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| **Signature:** |  |
| **Date:** |  |

**Employees/subjects, who witnessed the assessment:**

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| **Name of Employee/Subject** | **No. of Procedure** | **Name of Test Activity** | **Comments** |
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**Preparation for the assessment:**

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| **Procedure No.** | **Name** | **Applicative document** |
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| **Name and number of Uncertainty evaluation's documents** | **Name and number of Validation's documents** |
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| **Review of procedures and documents:** **🞏 There are no comments on procedures / documents reviewed****🞏 There are some comments on procedures / documents reviewed****Reference to comments issued:** |
| **newlogo****Opening meeting** **> Introduction & mutual acquaintance (members function, request for cooperation).****> ISRAC's assessment:** **- is based on ISO/IEC 17011** **- is only a sample** **- Assessors will have internal discussion** **(Presentation of the forms to be used).****> Accreditation purpose (voluntary,** **including this visit)****> Assessment: objectives and Scope (Plan).** **Including: follow up on corrective action, implementation of ISRAC requirements.****> Arrangements** **- Availability of resources and facilities.** **- Emergency procedures** **- One lab representative should accompany each assessor (to approve finding by his/her signature).**  **- The consultant function.** **- A room for assessors for discussion****> Confidentiality.****> Planned time for wrap up meeting (method & details).****> Question from lab team.****> A tour in the lab (when required).** |  | **newlogo****Wrap up meeting** **> Many thanks (to Lab team & assessors).****> The randomality of the assessment.****> Introduction:** **- Assessment report (up to 14 days following assessment).** **- Corrective action (up to 20 days)** **- Explanation of corrective actions*** **Reply + evidence for implementation**
* **Systemic reply**

**> Confidentiality****> Surveillance agreement (signed by authorized business personal)****> The assessment (Performance Vs Plan).****> Compliances presentation (Lead assessor).** **- Compliance (positive)** **- Non-compliances (way of grading the non-compliances)****> Non-compliances presentation (Technical assessors).****> Signature on in compliances forms****> Discussion & questions.****> Meeting close.** |

**Non-conformities are classified by ISRAC into three levels:**

**Level 3 is assigned to non-conformities when the professional competence of the organization is not questioned but a deviation from procedures or standards is suspected.**

**Level 1 is assigned to non-conformities that disrupt directly the quality of the published results or due to a flaw in the organization’s quality system that might lead to a system failure.**

**Failure to correct the non-conformity within a specified period of time may result in the removal of accreditation**

**Level 2- A group of level 3 non-conformities, repeating the same type of problem shall be classified as level 2 non-conformity.**

**For findings in level 1 and 2 the CAB has the obligation to suggest appropriate corrective actions as a condition for closing the assessment.**

**Comment – when a finding is not in the scope of accreditation or the assessor chooses to comment on something, it is classified as a comment.**

**Comment: *the classification is given during the assessment by each assessor in its field.***

**If there is disagreement over the classification of the non-conformity than the Lead Assessor’s opinion rules**

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| Highlights for the Assessment Report Clause and question to be addressed |
| **ISO/IEC 17025 clause 5.2.1****- Is it your impression that the employees have demonstrated suitable practices?****- Is it your impression that employees are familiar with the limitations of the testing/ calibration methods?****- What are your comments on group leaders and their technical expertise?** |  |
| **ISO/IEC 17025 clause 5.3** **Environnemental conditions, accommodation** |  |
| **ISO/IEC 17025 clause 5.4.2** **Is it your impression that the organization documents presented are clear and present appropriate testing/ calibration methods?** |  |
| **ISO/IEC 17025 clause 5.4.5** **Are the methods validated? Please comment on comprehensiveness and correctness of method validations and on the quality of relevant records?** |  |
| Clause and question to be addressed  | Highlights for the Assessment Report |
| **ISO/IEC 17025 clause 5.4.6** **Are the uncertainty calculations in place? Please comment on the correctness and comprehensiveness of the uncertainty calculations.****Concerning calibration laboratories: if the CMC values presented are realistic and justified? Are they presented fully and correctly in the accreditation schedule?** |  |
| **ISO/IEC 17025 clause 5.5** **Laboratory equipment, conditions, calibrations, history** |  |
| **ISO/IEC 17025 clause 5.6** **Traceability - Please comment on traceability imported from higher level calibration laboratories and the dissemination inside the laboratory, when relevant** |  |
| **ISO/IEC 17025 clause 5.4.7** **Control of data** |  |
| **ISO/IEC 17025 clause 5.9** **Assuring the quality of results (PT, ILC any other means)** |  |
| Clause and question to be addressed  | Highlights for the Assessment Report |
| **ISO/IEC 17025 clause 4.13** **- Quality and correctness of technical records.****-Correctness and clearness of scope of accreditation** |  |
| **ISO/IEC 17025 clause 5.10** **Do the testing/ calibration certificates meet the accreditation standard / regulatory requirements?**  |  |
| **Implementation of corrective actions from previous visit**  |  |
| **Is the activity presented eligible for accreditation?** **Yes / No Detail:** |  |

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| **Highlights for the next assessment** |
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**Assessment notes and records - Please write as legible as possible**

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