|  |  |  |
| --- | --- | --- |
| תאריך: |  | Date: |
| סימוכין: |  | Reference: |

**מחברת טיוטה לבודק**

**OBSERVATION NOTEBOOK**

# יש לכתוב בעט כחולה

# All notes should be made with a blue pen

|  |  |  |
| --- | --- | --- |
| שם הארגון |  | **Name of organization** |
| מספר הארגון |  | **ISRAC Lab. No:** |
| סוג המבדק |  | **Assessment type** |
| התחום/טכנולוגיות הנבדק/ות |  | **Assessed fields** |

|  |  |  |
| --- | --- | --- |
| נציג הארגון (מלווה לבודק) |  | **Organization representative** |
| שם הבודק |  | **Assessor's name** |
| סוג האתר |  | **Site type** |
| תאריכי מבדק |  | **Assessment dates** |
| הרחבה מבוקשת |  | **Requested extension** |

|  |  |  |
| --- | --- | --- |
| **The document is saved:**  | In paper 🞏בנייר Electronically 🞏 אלקטרוני | המסמך שמור |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| חתימת בודק מוביל: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Lead Assessor signature | תאריך: | \_\_\_\_\_\_\_\_\_ |
| חתימת הבודק: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Assessor signature | תאריך: | \_\_\_\_\_\_\_\_\_ |

Employees/subjects, who witnessed during the assessment.

עובדים / נושאים אשר נצפו במהלך המבדק :

|  |  |  |  |
| --- | --- | --- | --- |
| **Name of Employee/Subject** **שם העובד / נושא** | **Name of Test Activity** **שם הבדיקה / פעילות** | **No. of Procedure** **מס' הנוהל** | Commentsהערות |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

Documents that were read as preparation for the assessment

מסמכים שנקראו כהכנה למבדק

|  |  |  |
| --- | --- | --- |
| **Applicative document** **מסמך יחוס לשיטה**  | **שם Name**  | **Procedure No.****מספר נוהל** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

|  |  |
| --- | --- |
| Name and number of Validation's documents**שם ומספר מסמכי ולידצי**ה | Name and number of Uncertainty evaluation's documentsשם ומספר מסמך הערכת אי ודאות  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

|  |
| --- |
| Review of procedures and documents: 🞏There are no comments on procedures / documents reviewed🞏There are some comments on procedures / documents reviewedReference to comments issued: |
| **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). |  | **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 (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

| Emphasizes for the Assessment Report דגשים לדוח מבדקClause 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? |
| Emphasizes for the Assessment Reportדגשים לדוח מבדק | Clause and question to be addressed  |
|  | 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) |
| Emphasizes for the Assessment Reportדגשים לדוח מבדק | Clause and question to be addressed  |
|  | 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: |

|  |
| --- |
| Emphasizes for the next assessmentדגשים למבדק הבא  |
|  |

**Assessment notes and records**

|  |
| --- |
| Please write the notes legible as possible  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |
|  |