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

**מחברת טיוטה לבודק**

**OBSERVATION NOTEBOOK**

# יש לכתוב בעט כחולה

# All notes should be made with a blue pen

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

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

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

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| 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 :

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| **Name of Employee/Subject**  **שם העובד / נושא** | **Name of Test Activity**  **שם הבדיקה / פעילות** | **No. of Procedure**  **מס' הנוהל** | Commentsהערות |
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Documents that were read as preparation for the assessment

מסמכים שנקראו כהכנה למבדק

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

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| Emphasizes for the next assessmentדגשים למבדק הבא |
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**Assessment notes and records**

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