Date: Click here to enter a date.

Reference:

To

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**Subject: Planning and Reporting an Assessment**

|  |  |  |
| --- | --- | --- |
| **שם הארגון** |  | Name of the Organization |
| **מספר הארגון** |  | Number of laboratory |
| **סטטוס הארגון** |  | Organization status |
| תאריך תוקף ההסמכה |  | Accreditation expiry date |
| סוג המבדק |  | Assessment type |
| תאריכי המבדק |  | Dates of the assessment |
| התקן/נים הנבדק/ים | ISO/IEC 17025:2017 | Standard reviewed |
| האתר |  | Site |
| **תאריך תכנון המבדק** |  | Date of planning the assessment |
| בודק מוביל |  | Team Leader |
| בודקים מקצועיים |  | Technical Assessors |
| צופים |  | Observers |
| יועץ |  | Advisor |
| שפת ביצוע המבדק ועריכת הדו"ח |  | Language of Assessment & Report |
| התחומים / הטכנולוגיות בהיקף ההסמכה |  | Scope of Accreditation  fields / technologies |
| תחומים/טכנולוגיות בהן יש היקף הסמכה גמיש (Type C) |  | Fields/Technologies in which a flexible scope of accreditation exists (Type C) |
| ההרחבה המבוקשת |  | Extension requested |

***An appointment of only one assessor under observation as trainee per assessment day.***

***Observers outside of ISRAC staff shall take part in the assessment in accordance with the assessment team and organization***

**Assessment Planning**

**Assessments activities and time table**

*Instructions to the assessor:*

*While planning an assessment, the following shall be considered: number of technologies, number of methods, number of qualified technicians, personnel qualifications, procedure completeness, participation in PT or ILC, validation data and uncertainty evaluation, assessment type and historical data (as well as normative).*

*The assessment techniques should be planned to include a combination of a vertical and horizontal assessment technique.*

Historical data of the assessed CAB to be considered during the assessment planning:

* *Results of Risk Survey from previous assessment and general risk management for the CAB (for consideration by the Team leader).*
* *Extent of cooperation with ISRAC and including CAB providing the required deliverables in due time, towards the assessment.*
* *Complaints concerning the CAB made to ISRAC during the period from the previous assessment and results of this query.*
* *Past non-conformities and their classification (in particular those classified as 1-2).*
* *It is required to assure implementation of corrective actions from the previous assessment to the relevant fields (time allocation).*
* *Employees or methods in the scope of accreditation not observed in the previous assessment.*

*Using good judgement and systematic review, any employees not observed in the previous assessment or required for additional observation must be included, people who have been observed and demonstrated gaps in knowledge or control of the test, new employees, etc. It is appropriate to specify specific names of persons to whom the assessor wishes to view.*

*In accreditation and re-accreditation assessments, at least one method per each technology shall be sampled for the assessment by professional assessors. Using good judgement and systematic review, any methods having impact on other methods.*

*It is appropriate to specify the type of the item or the measured/tested/calibrated/inspected item, with information to provide appropriate identification of the tested (process, equipment, measured parameter).*

*In CABs with flexible accreditation scopes (Type C), the relevant requirements shall be assessed according to procedure number 1-000016,*

1. *Before the assessment, the CAB shall submit the updated list to which the scope of accreditation refers*

*- The technical assessor shall examine the new subjects that have been included in the list and examine whether:*

* *There is a validation report*
* *New controls are required*
* *Relevant standard requirements are met*

*The Team Leader shall check that the CAB has established adequate procedures relating to the introduction of a new component in the list*

*It is required to assure that the CAB operates according to the Policy for Reporting of Results and Use of ISRAC Symbol, procedure number 1-45001. As long as the CAB refers on results of other accredited laboratories it is required to assure that information received from external sources shall be under accreditation as required in procedure number 1-455001. As long as the CAB doesn't use the symbol it cannot use information for which there is no evidence that it was performed under accreditation.*

*In laboratories having temporary sites, the nature of the activity should be emphasized:*

1. *The test performed at the reference site is identical in its format to that performed on the temporary site (customer site). There is no difference in the test equipment, the environmental and test conditions, the test procedure, the uncertainty in the test, the manner in which the test results are documented, the abilities and competence of the assessor, etc. In this case, elements related to the organization of the CAB should be checked in terms of packaging the required testing equipment, conveying of the equipment, acclimation of the equipment prior to testing, and verification of the equipment after returning to the reference site.*
2. *The test performed at the reference site is different in one or more parts of the test performed on the temporary site, and the difference may influence the test method or testing equipment. In this case, it is necessary to examine both the activity at the reference site and the activity performed on a temporary site.*
3. *The test performed at the reference site differs from the test performed at the temporary site only in the uncertainty values for the test. In this case, it is sufficient to examine the reference site and in addition, to assess the results of the examination of the components of the uncertainty balance, which reflects the differences in the conditions of the test, such as the stability of the environment conditions etc.*

*In CABs having field laboratories, it should be emphasized during reassessments as well as unannounced assessments, and also include assessment activities in the field laboratories, at least by the Team leader.*

*It is required to request to witness critical segments of the test based upon its nature as part of a systematic review of the assessment.*

*It shall be emphasized that actual witnessing is required unless other assessment techniques can provide equivalent information in order to assess the conformity assessment activities. The justification shall be documented in a form of a planned deviation.*

Fill in all the fields in the assessment plan below, when relevant, and verify:

* Representation of methods in relation to the assessed technologies (according to the principle day per technology) and in relation to the previous assessment, when relevant.
* Alignment between the technical plan and the allowed time.
* In an accreditation assessment combined with an extension assessment the extended methods shall be mentioned in the “remarks to the assessment plan” section.
* The methods for re-accreditation shall be appropriately sampled and in case the extension does not require additional payment, the required time for witnessing the extended method does not exceed two hours.

*It shall be emphasized that an actual witnessing is required unless other assessment techniques can provide equivalent information in order to assess the conformity assessment activities. The justification shall be documented as a planned deviation and in the Assessment Report's section "Assessment Summary – Planning vs. performance".*

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Date** | **Site** | Scope (A/C) \* | **Field/ technology** | **Assessor** | **Test Method (name)** | **Test method (detail of standard/ reference document) \*\*** | **The preparations required The preparations required including test/calibration/inspection item** | **Authorized employee required for observation** | **Comment** |
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\* For a CAB with a flexible (Type C) scope of accreditation it is required to assess the manner in which the scope is managed: Procedure, Responsible and approving person and the list of flexible compnents added since the last assessment.

\*\* Specify the standard/reference document as written in the scope of accreditation

Comment: if the CAB wishes to receive the regulator's recognition based upon the accreditation, he is entitled to invite the regulator to observe the relevant assessments performed by ISRAC.

Planning assessments for a multi-site organization

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| no Technology | 1Site | 2 Site | 3 Site | 4 Site | 5 Site |
| **1** |  |  |  |  |  |
| **2** |  |  |  |  |  |
| **3** |  |  |  |  |  |
| **4** |  |  |  |  |  |
| **Total number of technologies** |  |  |  |  |  |

|  |  |  |
| --- | --- | --- |
| היקף הסמכה גמיש (Type C) | Yes  No | Flexible scope of accreditation (Type C) |
| הערות לתכנית המבדק |  | Remarks to the assessment plan |
| הבודק המוביל  חתימה ותאריך |  | Team Leader  Signature and date |
| **סמנכ"ל/ראש אגף או ממלא מקום**  **חתימה ותאריך** |  | Deputy General Director/Head of Division or Deputy  Signature and date |

**Assessment Report**

**Assessment Summary**

Background on the laboratory:

*Instructions to the assessor:*

*The summary shall include* *the following points (the organization may be requested to prepare a summary. The request shall be referred to as part of preliminary preparations for the assessment in form number T2-623001-05):*

* *Changes in personnel;*
* *Workload compared to previous assessment, changes in personnel;*
* *Changes in structure and environmental conditions;*
* *Fulfillment of objectives;*
* *Drawing lessons from the results of improved and collaborating with internal and external customers;*
* *Organization’s achievements;*
* *Last accreditation date, assessment type and reasons for conducting it.*

Planning vs. performance:

*Instructions to the assessor:*

* *Evaluation of the degree of implementation will be carried out against the program written by the assessor, specifying the reasons for non-compliance with the plan or significant time changes and/or assessed personnel (when relevant). In case the assessment technique deviates from the original assessment plan method the assessment plan specific reason*

Cooperation:

*Instructions to the assessor:*

* *Evaluation of the extent of cooperation received by the assessment team from the laboratory before and during the assessment. Cases should be noted in which the assessment team encounters situations that indicate difficulty. It is important to detail and relate to them as part of ISRAC’s risk management, for example: presentation of updated procedures, validation documents and reference documents in preparation for the assessment, performance of the required preparations for the assessment, availability of documents during the assessment, availability of employees, availability of sites and work stations, time and logistics, etc…*

**Names of Laboratory representatives in the opening and closing meeting:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Duty** | **Opening meeting** | **Closing meeting** |
|  |  |  |  |
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**Assessment Observations**

**Non-conformities forms**

Total number of forms: ­\_\_\_\_ Toal number of Non-conformities: \_\_\_\_ Total number of remarks: \_\_\_\_

|  |
| --- |
| Addition of the non-conformities forms from the assessment  Not relevant – handed during the assessment |

**Summary of assessment finding**

**Comment:**

**The highlighted markings are recommendations for improvement that did not reach the conclusion. It is suggested that the laboratory consider using these comments to improve processes:**

הנחיות לבודק: Instructions to the assessor

|  |  |
| --- | --- |
| *סעיפים שנבדקו ואין הערות לשיפור ו/או שימור יש לציין מה נבדק ומשפט מסכם לדוגמא: "במבדק הנוכחי לא עלו נקודות לשיפור" או "אין הערות למסמכים שהוצגו במהלך המבדק" יש לציין את המסמכים שנסקרו.* | *Sections that were examined and there are no comments for improvement and/or preservation, please note what has been examined and a summary sentence for example: "In the current assessment no points for improvement were raised" or "There are no comments on the documents presented during the assessment" Please note the documents reviewed.* |
| *בכל סעיף כשרלוונטי, יש לציין תצפיות ועובדות, המעידות על מצבים של חוסר התאמה לדרישות ההסמכה ונהלי הארגון שלא באו לכדי ממצא. כשניתן ומתאים לציין ליד התצפית מידת ההתאמה לדרישות ההסמכה ונהלי הארגון. יש לבחור במשפט המציג את הקשר בין התצפית למבדק הנוכחי* | *In each section when applicable, please note observations and facts, indicating situations where the organization do not meet the standard requirements and did not come into a finding. When possible and appropriate please note following the observation the level of conformance to the accreditation requirements and the laboratory procedures.* |
| *הסעיפים המודגשים באפור הם סעיפי חובה להתייחסות הבודק המקצועי.*  *יש להתייחס להטמעת פעילות מתקנת לממצאי מבדק קודם.*  *הערכת הבודק המקצועי לכשירות המעבדה.* | *The sections in grey are mandatory for the technical assessor.*  *The implementation of corrective action from previous assessment NCs should be taken into account.*  *Evaluation of the technical assessor for laboratory competency.* |

| **מס' סעיף**  Section | **שם הסעיף (לעיתים מקוצר)**  Name of section | **כן נבדק**  Assessed | **לא נבדק**  Not Assessed | **נבדק חלקית**  Assessed Partially | **הערה**  Comment | **סיווג לא חמור**  Minor classification | **סיווג חמור**  Major classification |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 4.1 | אי משוא פנים  Impartiality |  |  |  |  |  |  |
|  | | | | | | | |
| 4.2 | סודיות  Confidentiality |  |  |  |  |  |  |
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| 5.0 | דרישות מבנה ארגוני  Structural requirements |  |  |  |  |  |  |
|  | | | | | | | |
| 6.2 | כוח אדם  Personnel |  |  |  |  |  |  |
|  | | | | | | | |
| 6.3 | מתקנים ותנאי סביבה  Facilities and environmental conditions |  |  |  |  |  |  |
|  | | | | | | | |
| 6.4 | ציוד  Equipment |  |  |  |  |  |  |
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| 6.5 | עקיבות מטרולוגית  Metrological traceability |  |  |  |  |  |  |
|  | | | | | | | |
| 6.6 | שירותים ומוצרים מסופקים  Externally provided products and services |  |  |  |  |  |  |
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| 7.1 | סקר בקשות מכרזים והסכמים  Review of requests, tenders, and contracts |  |  |  |  |  |  |
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| 7.1.3 | כלל החלטה  Decision rule |  |  |  |  |  |  |
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| 7.2 | בחירת שיטות, אימות ותיקוף שיטות  Selection, verification and validation of methods |  |  |  |  |  |  |
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| 7.3 | דיגום  Sampling |  |  |  |  |  |  |
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| 7.4 | טיפול בפריטים לבדיקה /כיול  Handling of test or calibration items |  |  |  |  |  |  |
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| 7.5 | רשומות טכניות  Technical records |  |  |  |  |  |  |
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| 7.6 | הערכת אי ודאות  Evaluation of measurement uncertainty |  |  |  |  |  |  |
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| 7.7 | הבטחת תקפות התוצאות  Ensuring the validity of results |  |  |  |  |  |  |
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| 7.7.2 | השוואות בינמעבדתיות/PT  Interlaboratory comparisons/proficiency testing. |  |  |  |  |  |  |
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| 7.8 | דיווח תוצאות  Reporting of results |  |  |  |  |  |  |
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| 7.8.6 | דיווח תואמות למפרט  Reporting statements of conformity |  |  |  |  |  |  |
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| 7.8.7 | דיווח חוות דעת ופרשנויות  Reporting opinions and interpretations |  |  |  |  |  |  |
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| 7.9 | תלונות  Complaints |  |  |  |  |  |  |
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| 7.10 | חריגות  Nonconforming work |  |  |  |  |  |  |
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| 7.11 | בקרת נתונים וניהול מידע  Control of data and information management |  |  |  |  |  |  |
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| 8.1 | דרישות מערכת האיכות -אפשרות A  Management system requirements- Option A |  |  |  |  |  |  |
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| 8.2 | ניהול מערכת התיעוד  Management system documentation |  |  |  |  |  |  |
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| 8.3 | בקרת תיעוד  Control of management system documents |  |  |  |  |  |  |
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| 8.4 | בקרת רשומות  Control of records |  |  |  |  |  |  |
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| 8.5 | זיהוי סיכונים והזדמנויות  Actions to address risks and opportunities |  |  |  |  |  |  |
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| 8.6 | פעילות שיפור  Improvement |  |  |  |  |  |  |
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| 8.7 | פעולות מתקנות  Corrective actions |  |  |  |  |  |  |
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| 8.8 | מבדקים פנימיים  Internal audits |  |  |  |  |  |  |
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| 8.9 | סקרי הנהלה  Management reviews |  |  |  |  |  |  |
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| הנחיות רשות  ISRAC procedures | |  |  |  |  |  |  |
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| דיווח תוצאות ושימוש בסמליל הרשות ו/או מורכב  Reporting of Results and Use of ISRAC and/or Combined Symbol | |  |  |  |  |  |  |
|  | | | | | | | |
| היקף הסמכה  Scope of accreditation | |  |  |  |  |  |  |
| היקף הסמכה קשיח Type A-  היקף הסמכה גמיש Type C - | | | | | | | |
| דרישות נוספות  Additional requirements | |  |  |  |  |  |  |
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| **הטמעת פעולות מתקנות ממבדק קודם Implementation of corrective actions from previous assessment** | |
| סימוכין Reference  מספר אי ההתאמה ומועד המבדק  Finding number and assessment date | סטטוס מענה Response status  חלקי ונרשם ממצא חוזר/ Partial and a repeated finding noted/  ניתן מענה ונמצאה הטמעה Answered and implemented |
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**Witnessing of Performance:**

**During the assessment, the following activities were evaluated:**

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| --- | --- | --- | --- | --- | --- |
| העובד  Employee | מיקום הצפייה  Place of witnessing | שם הבדיקה/פעילות  Name of test/activity performed | תיאור הפריט לבדיקה/כיול/פיקוח  Description of the test/calibration/inspection item | מספר נוהל הארגון\*\*  Procedure No. | הערות  Comments |
|  |  |  |  |  |  |
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|  |  |  |  |  |  |

\*\* Document the organization’s procedure or SOP number

**General Summary**

*Instructions to the assessor:*

*The summary will convey key messages to those who have not read the entire report. Even if there is a return, the main issues that require attention should be brought to attention to significant points for improvement. Those who read it will only understand the main points of improvement and what are the points of reference.*

*It is important to use sentences that link the observation to the current test only.*

*Points to be addressed in the summary section:*

* *Witnessing report of the technical assessor presenting the points*
* *Presenting findings which have a transverse expression*
* *Way to maintain traceability and details of the relevant sections for improving and maintaining traceability*
* *Evaluation of the quality system's ability to influence the laboratory’s performance (e.g. planning versus execution)*
* *Evaluating the effectiveness of using QA tools to reduce the risk of production and release the wrong result.*
* *Summary of results of PT or other comparison tests and actions taken following results should be presented.*
* *It should be noted that proper activity and the welcome initiative of employees to improve the quality assurance of work processes.*
* *A declaration by the assessor regarding the fitness of the organization, according to procedures and the assessment of the organization's compliance with the accreditation requirements.*

Comment: if the CAB wishes to receive the regulator's recognition based upon the accreditation, the regulator is entitled to request the assessment report from the CAB.

Surveillance assessment, reassessment

The organization is reuqired to provide documentation for performance of corrective actions within 20 days (working days), from the last assessment day. In case that this is not possible, a new timeline is reuqired. In addition, the organization is reuqired to perform transverse corrective actions and add evidence.

First assessment, extention assessment

Handling of all non-conformities (including the verification of corrective actions, and ISRAC approval), shall be completed within 6 months from the day of the assessment. It should be noted that in case the handling of the corrective actions lasts more than 6 months from the day of the assessment, an additional assessment shall be performed in order to assure the implementation of the accreditation requirements.

(For details see ISRAC’s procedures published at ISRAC web-site: [www.israc.gov.il](http://www.israc.gov.il)).

Best regards,

|  |  |  |
| --- | --- | --- |
| הבודק המוביל  חתימה ותאריך |  | Team Leader  Signature and date |
| **סעיפים מקצועיים בדו''ח (מסומנים ברקע אפור) בוקרו ע''י: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **מאשר: סמנכ"ל/ראש אגף או ממלא מקום**  **חתימה ותאריך** |  | Technical sections in the report (highlighted in grey) were approved by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Approver: Deputy General Director/Head of Division or deputy  Signature and date |