Date: Click here to enter a date.

Reference:

To

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

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

**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 |  | Standard reviewed |
| האתר |  | Site |
| **תאריך תכנון המבדק** |  | Date of planning the assessment |
| בודק מוביל |  | Lead Assessor |
| 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 |
| 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 assessors 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).*

*Surveillance assessments after first accreditation, it shall be verified that corrective actions from the first assessment have been implemented.*

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.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Date** | **Site** | **Field/ technology** | **Assessor** | **Test Method (name)** | **Test method (detail of standard/ reference document) \*** | **The preparations required** | **Authorized employee required for observation** | **Comment** |
|  |  |  |  |  |  |  |  |  |
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\* Specify the standard/reference document as written in the scope of accreditation (not the number of procedure/organization number)

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** |  |  |  |  |  |

|  |  |  |
| --- | --- | --- |
| הערות לתכנית המבדק |  | Remarks to the assessment plan |
| הבודק המוביל  חתימה ותאריך |  | Leader Assessor  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).*

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:**

*Instructions to the assessor:*

*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 assesmnt no points for improvement were raised" or "There are no comments to the documents presented during the assesment" Please note the documents reviewed.*

*In each section when applicable, please note observations and facts, indicating situations where the organiztion do not meet the standard requirments, and did not come into a finding.. When possible and appropriate plaese note following the observation the level of conformance to the accreditation requirements and the laboratory procedures.*

| **מס' סעיף**  Section | **שם הסעיף (לעיתים מקוצר)**  Name of section | **כן נבדק**  Assessed | **לא נבדק**  Not Assessed | **נבדק חלקית**  Assessed Partially | **הערה**  Comment | **סיווג 3**  Classifica-tion | **סיווג 2**  Classifica-tion | **סיווג 1**  Classifica-tion |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 4.1 | ארגון  Organization |  |  |  |  |  |  |  |
|  | | | | | | | | |
| 4.2 | מערכת איכות  Management system |  |  |  |  |  |  |  |
|  | | | | | | | | |
| 4.3 | בקרת מסמכים  Document control |  |  |  |  |  |  |  |
|  | | | | | | | | |
| 4.4 | סקר בקשות להצעת מחיר  Review of requests, tenders and contracts |  |  |  |  |  |  |  |
|  | | | | | | | | |
| 4.5 | קבלנות משנה  Subcontracting of tests and calibrations |  |  |  |  |  |  |  |
|  | | | | | | | | |
| 4.6 | רכישת שירותים וטובין  Purchasing services and suppliers |  |  |  |  |  |  |  |
|  | | | | | | | | |
| 4.7 | שירות לקוח  Service to the customer |  |  |  |  |  |  |  |
|  | | | | | | | | |
| 4.8 | תלונות  Complaints |  |  |  |  |  |  |  |
|  | | | | | | | | |
| 4.9 | בקרת אי התאמה  Control of nonconforming testing and/or calibration work |  |  |  |  |  |  |  |
|  | | | | | | | | |
| 4.10 | שיפור מתמיד  Improvement |  |  |  |  |  |  |  |
|  | | | | | | | | |
| 4.11 | פעולה מתקנת  Corrective action |  |  |  |  |  |  |  |
|  | | | | | | | | |
| 4.12 | פעולה מונעת  Preventive action |  |  |  |  |  |  |  |
|  | | | | | | | | |
| 4.13 | בקרת רשומות  Control of records |  |  |  |  |  |  |  |
|  | | | | | | | | |
| 4.14 | מבדקים פנימיים  Internal audits |  |  |  |  |  |  |  |
|  | | | | | | | | |
| 4.15 | סקרי הנהלה  Management reviews |  |  |  |  |  |  |  |
|  | | | | | | | | |
| 5.2 | עובדים  Personnel |  |  |  |  |  |  |  |
|  | | | | | | | | |
| 5.3 | מבנה ותנאי סביבה  Accommodation and environmental conditions |  |  |  |  |  |  |  |
|  | | | | | | | | |
| 5.4 | שיטות בדיקה וכיול ותיקופן  Test and calibration methods and method validation |  |  |  |  |  |  |  |
|  | | | | | | | | |
| 5.4.6 | הערכת אי ודאות  Estimation of uncertainty of measurement |  |  |  |  |  |  |  |
|  | | | | | | | | |
| 5.5 | ציוד  Equipment |  |  |  |  |  |  |  |
|  | | | | | | | | |
| 5.6 | עקיבות המדידה  Measurement traceability |  |  |  |  |  |  |  |
|  | | | | | | | | |
| 5.7 | דגימה  Sampling |  |  |  |  |  |  |  |
|  | | | | | | | | |
| 5.8 | שינוע פריטים  Handling of test and calibration items |  |  |  |  |  |  |  |
|  | | | | | | | | |
| 5.9 | הבטחת איכות התוצאה  Assuring the quality of test and calibration results |  |  |  |  |  |  |  |
|  | | | | | | | | |
| 5.9.1 ב' | השתתפות בהשוואה בין-מעבדתית או בתכניות לבדיקת מיומנות  Participation in ILC or PT program |  |  |  |  |  |  |  |
|  | | | | | | | | |
| 5.10 | דיווח התוצאות  Reporting of results |  |  |  |  |  |  |  |
|  | | | | | | | | |
| הנחיות רשות  ISRAC procedures | |  |  |  |  |  |  |  |
|  | | | | | | | | |
| דרישות נוספות  Additional requirements | |  |  |  |  |  |  |  |
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| **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:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| העובד  Employee | מיקום הצפייה  Place of witnessing | שם הבדיקה/פעילות  Name of test/activity performed | מספר נוהל הארגון\*\*  Procedure No. | הערות  Comments |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

\*\* 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.*

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 |  | Leader Assessor  Signature and date |
| **מאשר: סמנכ"ל/ראש אגף או ממלא מקום**  **חתימה ותאריך** |  | Deputy General Director/Head of Division or Deputy  Signature and date |