Israel Laboratory Accreditation Authority

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ISRAC and its Accreditation Process Guidance and Requirements

Procedure Number **1-611002E**

Authorized by: **מאשרים:**

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הרשות הלאומית להסמכת מעבדות ISRAC (Israel Accreditation) הוקמה בחוק על ידי ממשלת ישראל כארגון ההסמכה הלאומי לבדיקה והסמכה של כשירות מקצועית בתחום כיול ובדיקה.

הרשות מוכרת במסגרת הסכם ההכרה ההדדי של הארגון הבינלאומי ILAC (International Laboratory Accreditation Cooperation) כעובדת על פי הכללים הבינלאומיים להסמכה.

הרשות הלאומית להסמכת מעבדות

Israel Laboratory Accreditation Authority

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עדכונים:

The Change השינוי ומהותו	סעיף Section	תאריך Date
Update of policy for conducting surveillance assessments after initial accreditation – report form number 1745.	3.9	29.08.2019

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FROM THE GENERAL MANAGER

Israel Laboratory Accreditation Authority (ISRAC) is a corporation that was established by law (The Israel Laboratory Accreditation Authority Law, 1997).

The vision behind the establishment and operation of ISRAC is to: "**Promote the quality and professional competence of conformity assessment and examination bodies in harmonization with the world, for the well-being of the state of Israel and its citizens**".

Accreditation is defined as an official recognition in the professional competence of the organization to perform certain tests/calibrations/inspection/services and certification procedures. Accreditation is open to all calibration/test laboratories as well as other conformity assessment bodies both in the public sector and the private sector.

In the accreditation process ISRAC assesses whether:

- The organization can professionally and reliably perform specific calibrations / tests, inspections and certifications as detailed in the scope of accreditation requested by the organization.
- The organization's quality system complies with the relevant international standards such as ISO/IEC 17020, ISO/IEC 17025, ISO 15189, ISO/IEC 17043, IOS 17034 or others, and is fully documented and implemented.
- The organization complies with all the requirements of the Israel Laboratory Accreditation Authority (ISRAC) and with the specific professional requirements of its specialty.

The preparation process of an organization, for accreditation, is a long one including the writing of procedures, work plans and the establishment of a quality system that shall, together answer the requirements of the relevant standards and the accreditation requirements of ISRAC, according to the needs of the organization's clients. The length of the accreditation process varies between several months up to more than a year, depending on the scope of accreditation requested and the starting point of the organization.

Many different questions may arise during the accreditation process. Questions such as; what does this requirement mean? Is the work planned satisfactory? Is the equipment adequate? Are the right subjects reviewed and in the right places?

It must be clear that for ethical reasons, ISRAC's employees must abstain from offering consultation. They cannot answer questions on how to do things, but they will answer, willingly, any specific questions regarding, for example, what should be done or whether the actions taken are satisfactory?

ISRAC's employees shall do their best to ensure that its requirements and the international standards are clear and well understood and assist the organization throughout the process. So as to enable test, certification and inspection bodies in Israel to meet the international standard and offer their clients services on an international level.

Contact details and additional updated information can be found on ISRAC's website: www.israc.gov.il.

Wishing you success,

ISRAC General Manager

1. INTRODUCTION

1.1 The Advantages of accreditation

Accreditation is defined as an official recognition in the professional ability and competence of the organization to perform tests, calibrations or inspection services, according to the client's needs.

ISRAC can accredit test methods that are preformed according to standards, specifications of other normative documents or methods developed by the organization.

Accreditation is open to all types of inspection bodies and calibration/test laboratories, whether they are part of a factory or part of the public or private sector.

In addition, accreditation enables the organization to evaluate the work it performs in comparison with international standards. Accreditation is a managerial and marketing tool that offers the organization and its managers a way to ensure the credibility of their results and the efficient function of the organization.

These are the reasons why regulatory bodies and big buyers in Israel and all over the world prefer using accreditation in their process of recognition of conformity assessment bodies or their results.

Receiving accreditation from an objective national body provides official recognition and strong evidence that the organization's management has taken every possible precaution in order to ensure that its quality system is well implemented in the organization, thus providing high quality performance in tests/ inspections and certification processes. Such evidence may come to the organization's aid in court or when dealing with insurance companies.

In many cases, accreditation gives the organization an advantage over its competitors in public tenders, especially those commissioned by governmental bodies. The following government regulators require accreditation from labs working with them: the Ministry of Defense, the Ministry of Health, the Ministry of Environment, the Ministry of Economy and Industry (commissioner of standartization and works chief supervisor), the Ministry of Internal Affairs and the Ministry of National Infrastructures.

All government tenders relating to testing require laboratory accreditation where relevant.

Important! **Accreditation provides official recognition of the organization's abilities, thus ensuring its clients of receiving trustable, high quality and comparable results.**

ISRAC has signed a mutual recognition arrangement with all the international accreditation bodies' ILAC (International Laboratory Accreditation Cooperation) signatories to ILAC Arrangement. ISRAC also has a contract of cooperation with the EA (European Accreditation). The government of Israel

signed a mutual recognition agreement with European community and the OECD countries (Organization Economic Cooperation and Development) on the subject of Good Laboratory Practice (GLP).
Using an inspection body accredited or recognized for GLP allows the exporter a commercial advantage. Information on ISRAC, the recognition process for GLP, forms for the initiation of the accreditation/ recognition process etc. can be found on ISRAC's website www.israc.gov.il. An accredited body enjoys advantages, International recognition and trust in its technical competence.

ISRAC recognizes research facilities working according to GCLP (Good Clinical Laboratory Practice) as per document EMA/INS/GCP/532137/2010, Reflection Paper for Laboratories that perform the Analysis or Evaluation of Clinical Trial Samples (GCLP), of the European Medicines Agency. Information on ISRAC, the recognition process for GCLP, forms for the initiation of the accreditation/ recognition process etc. can be found on ISRAC's website www.israc.gov.il. The GCLP recognition system is national. The recognized test facility is responsible to make sure that the studies are recognized worldwide.

An accredited conformity assessment report or certificate is identified by the ISRAC logo. An accredited CAB (Conformity Assessment Body) has the right to print ISRAC's logo on its reports pending that at least one of the results reported in the document were performed under accreditation. Test results preformed not under accreditation shall be clearly marked to prevent the misleading of the CAB's clients and consumers.

All the procedures and documents mentioned in this document are published on ISRAC's website www.israc.gov.il, under publications\ procedures, including the procedure about using the ISRAC logo (see procedure number 1-455001: Policy for reporting of results and using of ISRAC symbol)

1.2 The Contribution of ISRAC to International Trade and Development

Accreditation organizations, like ISRAC, exist in most developed countries.
These organizations accredit bodies that are called conformity assessment bodies (CABs) and perform tests and inspection activity in different fields. (The name conformity assessment body comes from the fact that at the end of the process the organization issues a certificate detailing what was tested and whether the results conform to the relevant specifications such as a certain procedure or client requirements).

Conformity assessment bodies handle laboratory calibration tests, quality/ environment/ safety management systems testing and inspection in different areas.

The accreditation bodies have united under two international associations: ILAC- International Laboratory Accreditation Cooperation and IAF- International Accreditation Federation.

These accreditation bodies have adopted the following international standards:

ISO/IEC 17025: General Requirements for the Competence of Testing and Calibration Laboratories. The international standard used as the basis for accreditation of evaluation, measurement and calibration laboratories in their individual countries. This standard is present also as an Israeli standard (S.I.) in Hebrew.

ISO 15189: Medical Laboratories - Requirements for Quality and Competence.

The international standard used as the basis for medical laboratory accreditation.

ISO/IEC 17020: Conformity Assessment - Requirements for the Operation of Various Types of Bodies Performing Inspection.

The leading standard used for the accreditation of inspection bodies. This standard is present also as an Israeli standard (S.I.) in Hebrew.

ISO/IEC 17043: Conformity Assessment - General Requirements for Proficiency Testing.

The used for the accreditation the competence of reference material producers.

ISO 17034: General requirements for the competence of reference material producers.

The adoption of international standards enables the different countries to harmonize their assessment of conformity assessment bodies.

This harmonized approach enables different accreditation organizations that use similar accreditation systems, to sign mutual agreements, which are based on respect, trust and mutual acceptance of each other's accreditation systems.

In addition, the accreditation organizations employ worldwide proficiency tests and peer evaluations in order to establish mutual trust.

These international agreements under the umbrella of ILAC and IAF, are called Mutual Recognition Arrangements (MRA) and are necessary for the recognition of test results of an accredited conformity assessment body by the countries that are part of the agreement.

Every side in the agreement accepts the accreditation of the other associate members as if it was the one granting the accreditation to the conformity assessment bodies.

All the accreditation bodies that are part of such an agreement operate according to the ISO/IEC 17011 standard; Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies.

This developing framework of mutual recognition between accreditation bodies makes it possible for different organizations producing products or offering services to gain international recognition and for the tests of products/ merchandise to be accepted in the international market without retesting. Thus, mutual recognition leads to a significant decrease in expenses both for manufacturers and

importers\exporters, by canceling the need for repeated tests and long periods of storage of products in the target countries.

1.3 The Israel Laboratory Accreditation Authority: ISRAC

The Israel Laboratory Accreditation Authority – ISRAC is a statutory authority, body corporate. ISRAC was established by the Israeli Government, authorized by law in April 1997. ISRAC operates as an independent non-structural governmental body. ISRAC was established in order to meet the need for transparent, homogeneous and objective criteria for assessing laboratory's professional competence.
ISRAC is the official authority responsible for accreditation of conformity assessment body in Israel.
ISRAC's purpose is to allow harmonization and mutual recognition between the state of Israel and other countries regarding measurements, calibration and testing.
In addition, ISRAC aids the Israeli consumer in need of testing laboratories, calibration and measurements, directly or indirectly.
The world trade agreements signed under the World Trade Organization (WTO) also support the existence of a national laboratory accreditation body.

The supervising body for ISRAC's activities is the ISRAC Council, which is made up of seven members and whose chairman is the representative of the Israeli Council for Higher Education. Its members represent ministries, organizations of the users in the services of laboratory and delegates of the CABs.

1.4 The International Activities of the Israel Laboratory Accreditation Authority

1.4.1 ACCREDITATION

ISRAC is a member of the international organization ILAC. Thus, it is obligated, like all of ILAC's members, to work according to the international standard regarding accreditation bodies:
ISO/IEC 17011 – Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies.
ISRAC has signed a mutual recognition arrangement under ILAC and EA (European Accreditation) establishing that the accreditation bodies of the countries that are part of the arrangement shall recognize the test results produced by any lab accredited by ISRAC. The number of countries that are part of the arrangement is constantly on the rise and the list of countries and the agreement itself can be viewed on ISRAC's website www.israc.gov.il, subdirectory links or the ILAC website www.ilac.org.

1.4.2 GOOD LABORATORY PRACTICE - GLP

ISRAC is the sole designated representative of the State of Israel for the recognition of test facilities working according to GLP (Good Laboratory Practice) principles. It complies with the OECD

(*Organization for economic co-operation and development*) principles for organizations monitoring Good Laboratory Practice.

The state of Israel has a mutual recognition agreement regarding GLP with the European community and the OECD, thus ensuring mutual acceptance of data from countries signatories to these agreements. For additional information please refer to procedure number 1-611051: ISRAC and its accreditation process for GLP testing and research facilities acting according to OECD-GLP principles.

1.4.3 GOOD CLINICAL LABORATORY PRACTICE – GCLP

The State of Israel has established a recognition and monitoring system for GCLP as per document EMA/INS/GCP/532137/2010. The GCLP recognition system is national. The recognized test facility is responsible to make sure that the studies are recognized worldwide. For additional information please refer to procedure number 1-611052: ISRAC and its Recognition Process of Facilities according to GCLP.

1.5 ISRAC's roles and rights

- To define, with the Minister of Economy and Industry's approval, the areas and tests category that shall receive accreditation.
- To define the requirements for accreditation of tests/calibrations/measurement laboratories and inspection bodies.
- To ensure that accredited bodies fulfill the requirements of accreditation and accordingly continue or withdraw their accreditation.
- To serve as the sole designated representative of the state in all its areas of responsibility, including mutual recognition with accreditation authorities of other countries or international organizations.
- To initiate activities in the field of accreditation: training, publicity and promotion activities.

1.5.1 ISRAC Responsibilities

ISRAC's entire staff, including managers, assessors and consultants, signs a confidentiality agreement to secure any information received from clients.

In addition, the staff agrees to strict rules of conduct including: objectivity, transparency and avoiding conflict of interest. All this is published in ISRAC's, service charter ,which can be found on ISRAC's website home page at www.israc.gov.il. See procedure number 1-000020: Customer Service Treaty.

1.6 Areas of Accreditation by ISRAC according to ISRAC's website are detailed in appendix number 1 to this document and elaborated in document number T1-000016-03, table of technologies, published in ISRAC's website.

ISRAC is developing additional areas of accreditation in order to meet the demands of the Israeli market and its clients.

2. ACCREDITATION AND THE DIFFERENCE BETWEEN ACCREDITATION AND CERTIFICATION

Accreditation – the official recognition given to a conformity assessment body or certification body by a designated organization, affirming that the CAB has the professional capability for performing certain inspection, certification, test or calibration methods.

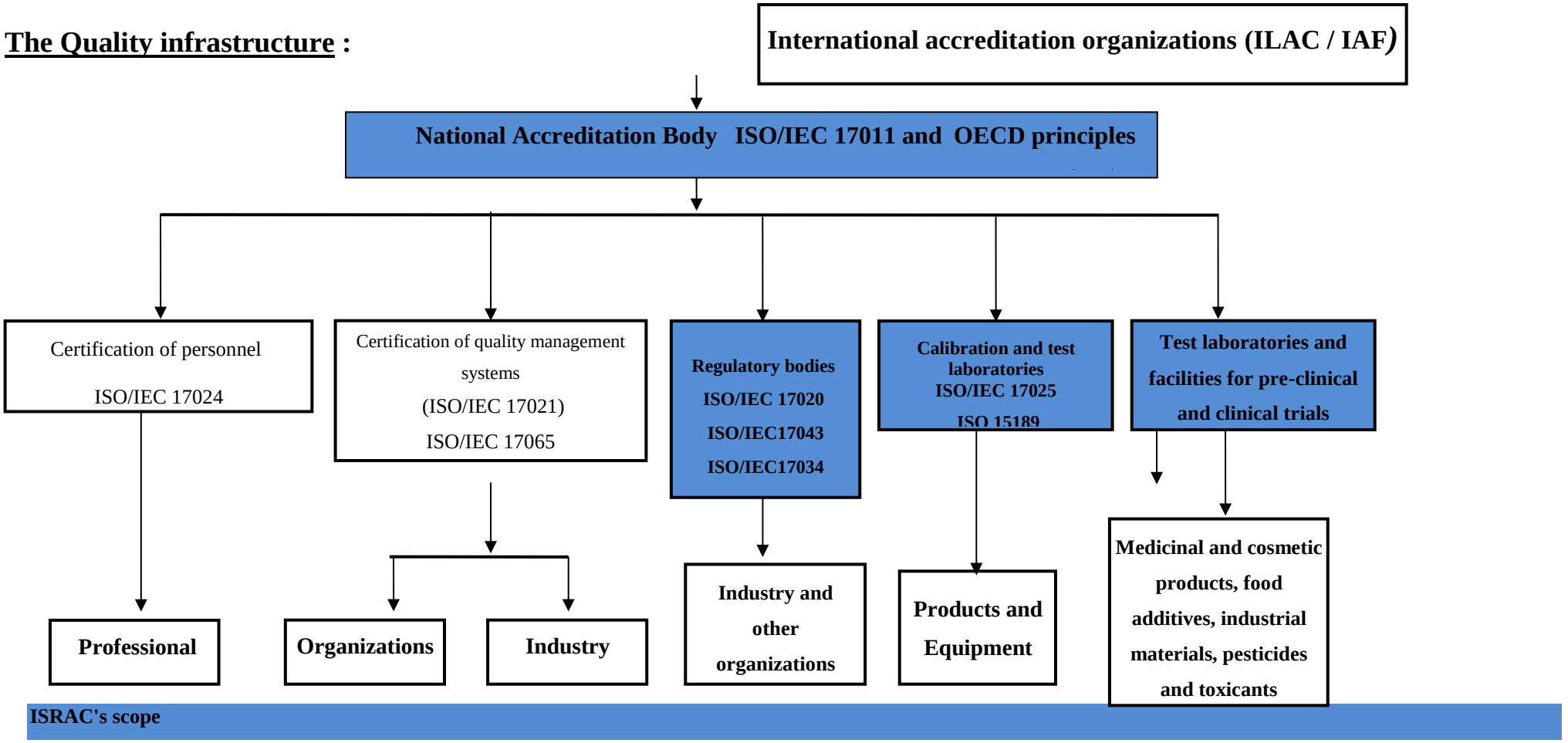
Accreditation is not granted to the entire CAB as a whole but to specific methods or areas of activity. Accreditation standards include entire chapters dealing with assessing the professional competence of the organization. For example, the standard for laboratory accreditation deals with subjects unique to laboratories such as validation of test methods, uncertainty of test methods, competence of laboratory personnel, environmental conditions for test performance, consistency of results, calibration of test equipment, sampling, handling and preparation of samples for testing, reference materials, proficiency testing etc.

Certification- a method by which a third party provides a written confirmation that a product, process or service complies with certain defined specifications. When certifying a laboratory according to the ISO 9001 standard, mainly the laboratory's quality management system is assessed but little can be learned about the professional and technical capacities of the organization or about its abilities to supply accurate and credible results.

Accreditation is granted to each test method separately as opposed to certification that is given to the entire organization and does not consider each method on its own.

The Israel Laboratory Accreditation Authority is a national body that was established by law in order to provide official recognition to an organization's professional capacities, thus enabling its clients to put their trust in the tests, measurements, calibrations and quality/environmental control system tests, performed by the organization.

The Quality infrastructure :



2.1 Candidates for accreditation

Any organization or body dealing with tests, inspection, etc. and is a legal entity or part of one, is a candidate for accreditation.

The organization is not limited to a certain number of employees and the only requirements are that it be an identifiable legal entity and that it performs inspection, testing, calibration and measurement activities.

ISRAC is committed to offer accreditation to any organization in the State of Israel, disregarding its location or distance.

A laboratory or inspection body that are part of a larger organization, can receive accreditation only after proving that their employees are free of external pressure or conflict of interest in issuing test reports. In order to ensure that is the case, ISRAC inspects the organizational structure and the contracts between the employees and employers to see that they are not directly subordinate to an interested party, which can apply undo pressure.

2.2 The Scope of accreditation-What is it and how it is defined

2.2.1 Scope of accreditation of laboratories

Accreditation is awarded to the specific tests for which the laboratory requests. It is not given to the entire laboratory as a whole. The organization's employees and managers are assessed in sample of methods in each technology for which they seek accreditation. A professional assessor, who is an expert in that area, evaluates every subject, technology and the tests included in its desired scope of accreditation.

Before commencing the accreditation procedure, each laboratory must define the areas and tests category in which it seeks accreditation, in the document "The scope of accreditation".

The document is published and is also attached to the accreditation certificate.

The scope of accreditation of each laboratory is published on ISRAC's website under www.israc.gov.il Accredited Laboratories. Search laboratories on ISRAC web site using the search engine provided by keyword or specific test reference document number, will provide details of all the accredited laboratories for those certain activity include refernce to the scope of accreditation.

Standard test methods are methods that were developed by organizations such as SII, EPA, FDA, ASTM and AOAC and were published as international standards. ISRAC recognizes these methods as standard and valid methods and the organization must prove their capability to achieve the standard determined characteristics in the laboratory based on a (verification procedure).

Non-standard test methods must be validated in order to receive accreditation (see section 2.3.2)

A separation must exist between tests/ calibrations performed at a temporary facility or at the client's facility. This fact must be presented to the clients in the accreditation scope. A temporary facility or field laboratory must work according to ISRAC's special requirements and policy, in order to ensure the credibility of the test results preformed

according to these methods. See procedure number 2-614002: Procedure for the Accreditation of a Multi-Site Organization on www.israc.gov.il.

2.2.2 Accreditation Types for Laboratories

The scope of accreditation of an inspection body or a testing or calibration laboratory is the formal and precise statement of the activities, which the laboratory is accredited for.
The term "flexible scope" was introduced several years ago and was accepted by the world. The idea was introduced in order to enable the laboratory to adjust its testing methods for customer needs on time, for details see procedure 1-000016: ISRAC policy and criteria for the construction of scope accreditation (appears on ISRAC website/publication/procedure).

3. THE ACCREDITATION PROCESS

3.1 The accreditation process has several stages, the main one being the period of self-preparation and implementation of the accreditation requirements according to the relevant standard, ISRAC's requirements and the specific technical documents.

During the process of accreditation, the organization's personnel are invited to meet with ISRAC's staff and participate in training sessions.

The stages in the accreditation process:

3.1.1 Filling out the "Presenting the organization" (Document number 1-611003) and the checklist for the relevant standards and specific documents for this field of accreditation, downloaded from ISRAC's website http://www.israc.gov.il/?CategoryID=223

3.1.2 Submitting the "Presenting the organization" documents, the completed checklist for the relevant standards and the organization's quality manual as required in procedure number 1-000014: The preliminary request for accreditation/ re accreditation/ extension of the scope of accreditation/ surveillances, together with the payment of the application fee. This initial fee accords the organization the right for a review of the documents presented for the evaluation of the organization readiness and the cost of the assessment.

3.1.3 The Head of the relevant Division shall contact the organization's representatives and shall pass on comments and clarifications on the reviewed material. The Head of Division shall coordinate the next stages in the process

3.1.4 Signing the "request for accrediting an organization" form and the cost estimates of the accreditation form. A pre-assessment can be coordinated in order to evaluate the organization's readiness for accreditation.

3.1.5 Payment of 50% of the cost of the assessment is a prerequisite for reviewing in depth the Organization's documents towards performing the assessment (see also procedure number A-621001: Financial Arrangements for the Process of Accreditation and Recognition

3.1.6 Submitting the organization's technical procedures.

3.1.7 Approval of the assessors, the accreditation scope and the date of assessment by the organization.

3.1.8 Review of the organization's technical procedures, by the assessors.

3.1.9 Performance of on site assessment.

3.1.10 If non-compliances are discovered during the assessment, the organization shall submit proposals for corrective actions and proof of their implementation.

3.1.11 The accreditation committee shall review the findings of the assessment and the corrective actions taken.

3.1.12 The accreditation committee shall pass its recommendation regarding the accreditation of the organization, to the General Manager.

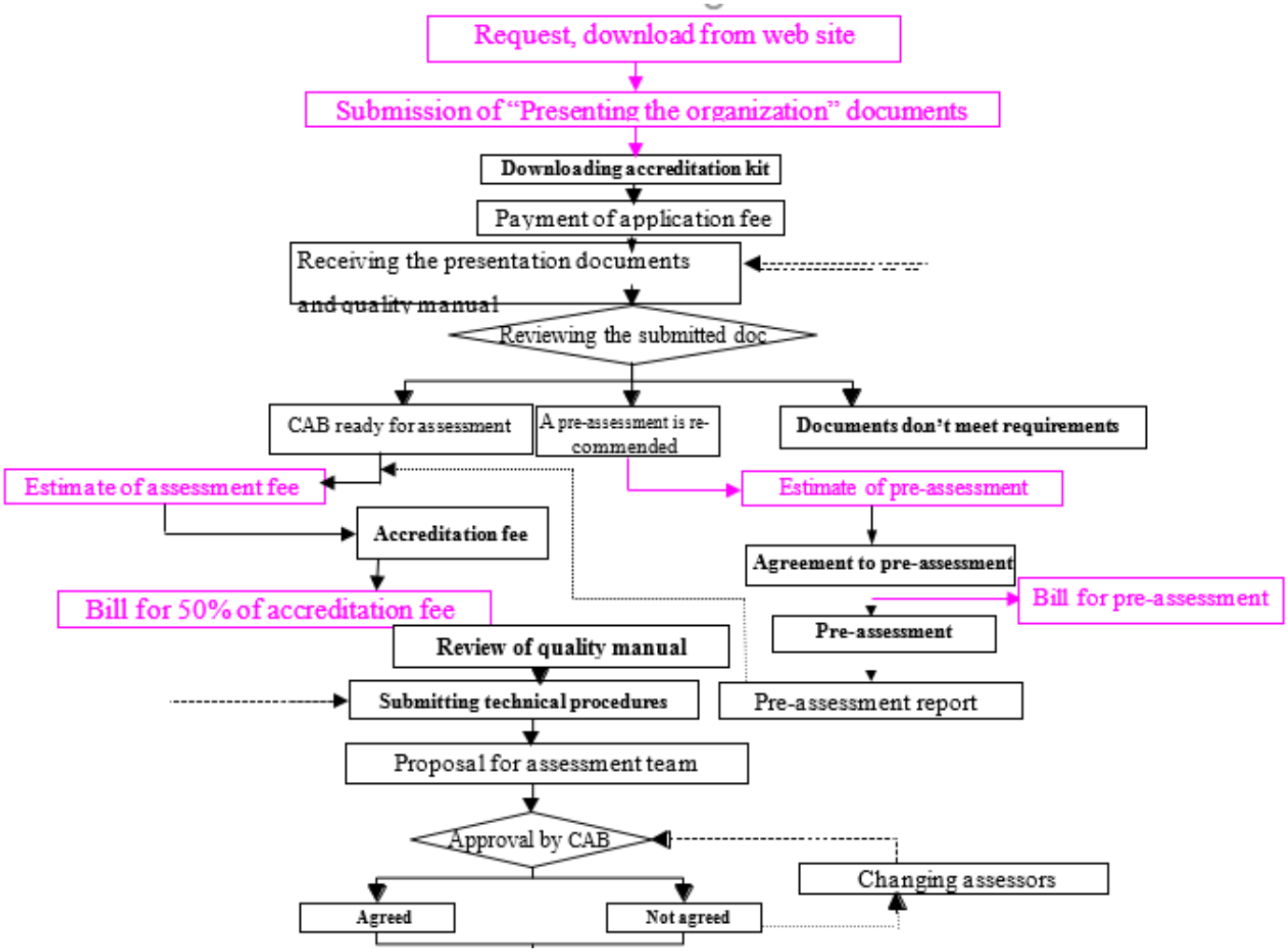
3.1.13 The General Manager decides regarding the accreditation of the laboratory.

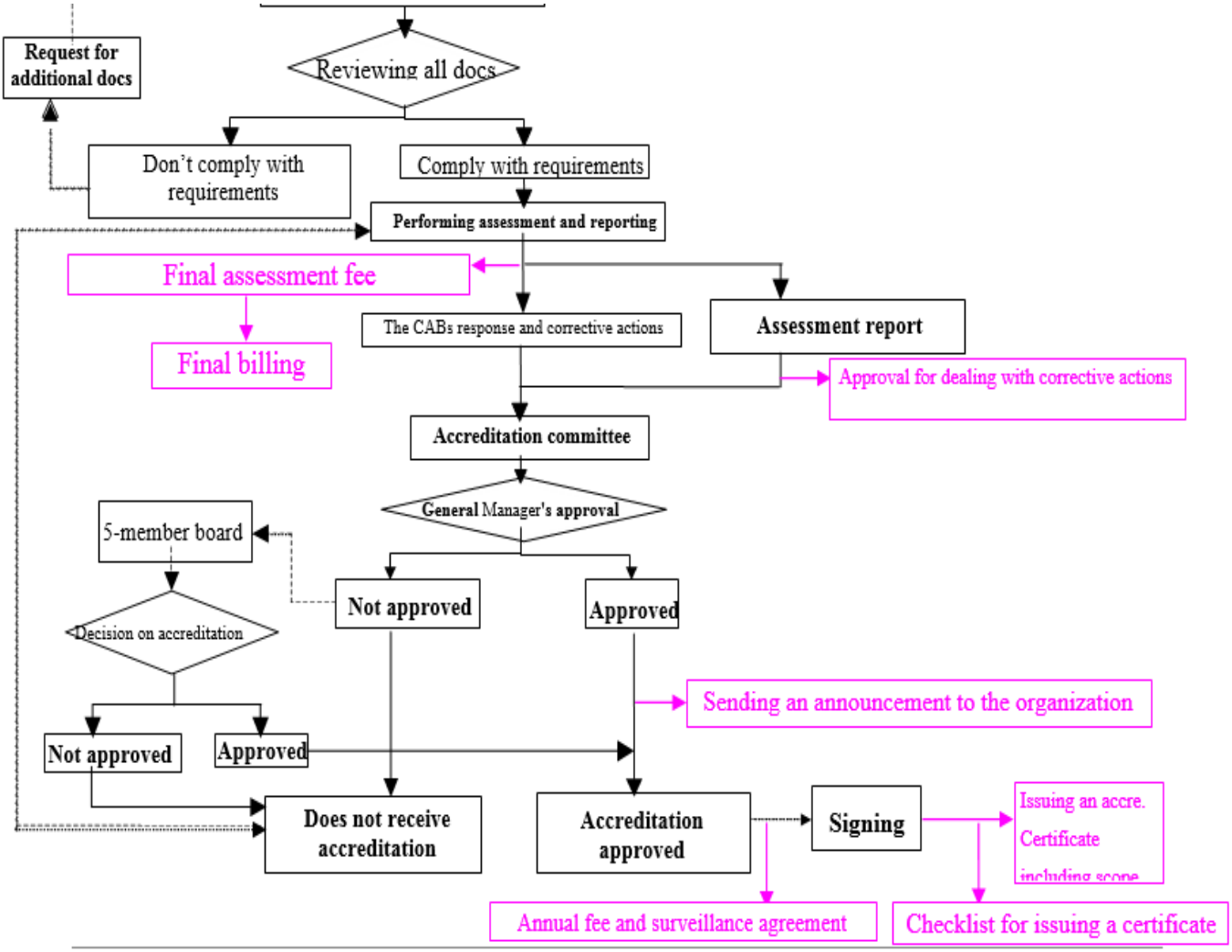
3.1.14 Signing a surveillance agreement with ISRAC.

3.1.15 Granting accreditation.

Note*: ISRAC's obliged time schedule for each accreditation stage can be found in details on ISRAC service convention on the ISRAC web site.*

The next page contains a flow chart describing the first accreditation process combined with the financial arrangements following the procedure.





3.2 Finding all the information regarding the accreditation process

The following documents are sources of information for an organization seeking accreditation

Accreditation is granted according to the most recent edition of the relevant standard written by ISO International Standard Organization.

Presented below is the list of relevant standards for organizations seeking accreditation, each organization according to its areas of expertise:

- ISO/IEC 17025; for test and calibration laboratories, except medical Laboratories;
- ISO 15189; for medical laboratories;
- ISO/IEC 17020; for inspection bodies;
- ISO/IEC 17043: for Proficiency Testing suppliers;
- ISO 17034: for the reference material producers;
- Published regulators' requirements on ISRAC website.

3.2.1 The organization can self assess whether it is in compliance with the relevant standard using a checklist compiled according to the standard. The checklist can be downloaded from ISRAC's website under the "request for accreditation" directory.

3.2.2 The "Presenting the organization" document, published on the ISRAC website will be filled by the organization as a statement to ISRAC.

3.2.3 The surveillance agreement signed with ISRAC, if the organization is found eligible for accreditation. A copy of the most recent version of the agreement can be found on ISRAC's website on the accreditation services/ surveillance agreement directory.

3.2.4 ISRAC's policy procedures and training documents, published on the website, on the publications directory: policy procedures, guidance documents and standard operating procedures.

3.2.5 ISRAC's guidance documents to the organization are published in ISRAC's quarterly newsletter, under "ISRAC's directions" and on the website on the publications directory/ ISRAC newsletter, and procedures no. 1-000014, 1-000019.

3.2.6 From time to time ISRAC shall publish guidance at ISRAC's website.

3.2.7 ISRAC's courses from which organizations receive training on the requirements of accreditation. The list of courses is published on the ISRAC website.

3.2.8 Specific requirements from regulatory authorities needed**,** in order to be recognized by the regulator. In such cases the regulator shall publish its specific requirements (usually in cooperation with ISRAC). If the organization is interested in recognition by the regulator it must implement these requirements.

3.2.9 ISRAC documents, procedures and guidance documents are published at ISRAC website: www.israc.gov.il .

3.3 Obligated Documents of the organization with regard to ISRAC

For the list of documents please refer to ISRAC procedure no. 1-432000 clause 8.6.

3.4 The documents that need to be submitted by the organization to ISRAC

3.4.1 The required documents are specified in document number 1-000014: Preliminary request for accreditation/ re accreditation/ extension the scope of accreditation/ surveillances.

3.4.2 Presenting the organization

The organization is required to describe itself using document number 1-611003: document presenting of the organization. This document is available on ISRAC website home page on the application for accreditation directory. This document includes a statement regarding:

3.4.2.1The legal entity of the organization

3.4.2.2 The scope of accreditation requested, detailing the technologies and test/calibration methods included in it.

3.4.2.3 The type of accreditation requested: fixed (Type A) or flexible scope(Type C).

3.4.2.4 Management and structure of the organization

3.4.2.5 Personnel and the procedures each employee is authorized to perform.

3.4.2.6 Description of the equipment

3.4.2.7 Subcontractors

3.4.2.8 Statement of participation in inter-laboratory proficiency testing

3.4.3 The organization's quality manual

The organization's quality manual encompasses all general procedures of the organization, which organize all the activities performed in the organization.

The manual forms the infrastructure, regulating all the activities performed in the organization. The quality manual can be organized in different ways (A general manual referring the reader to standard operating procedures or a detailed manual). ISRAC does not require adhering to a specific structure in writing the manual. The only criterion by which the manual is judged is whether the manual and the entire relevant quality document, address all the relevant standard's requirements.

Examples of subjects that may be addressed in the quality manual (this list should not be regarded as a final list but as an example):

3.4.3.1 The quality policy,

3.4.3.2 The organization's description, legal identity and organizational structure,

3.4.3.3 Training of personnel,

3.4.3.4 Document change control,

3.4.3.5 Complaints handling,

3.4.3.6 Internal audits,

3.4.3.7 Deviations and corrective actions,

3.4.3.8 Contract review with a new client,

3.4.3.9 Purchase of equipment,

3.4.3.10 Maintenance of equipment,

3.4.3.11 Validation of methods,

3.4.3.12 Form and contents of certificates,

3.4.3.13 Management review

3.4.4 Checklist

The checklist for accreditation is prepared according to the standard relevant to the organization's scope of activities. The checklist enables the organization to conduct self assessment the degree of implementation of the standard in its activities.

The checklist is to be completed by the organizations management and sent to ISRAC with the rest of the required documents as a statement of the organization's degree of compliance with the relevant standard.

All the documents and forms are available on the ISRAC website on the accreditation application directory.

3.5 Assessment at the Organization's Facility

After receiving all the required documents from the organization: "Presenting the organization" document, quality manual, checklist and technical procedures, if necessary, the documents shall be reviewed by the relevant Head of Division.

The Head of Division shall contact the organization for discussing the next stages it the accreditation process.

3.5.1 Pre-assessment

If the Head of Division concludes that there are significant gaps and the organization does not comply with the accreditation requirements, he may recommend a pre-assessment. An organization in the process of accreditation may also apply for a pre-assessment.

The pre-assessment shall be performed by one of the senior staff members of ISRAC and shall focus on the organization's quality system. The scope of accreditation required by the organization shall be discussed during the pre-assessment. The pre-assessment requires 1-2 workdays and will be planned as to evaluate whether the organization is ready for a full assessment. After the pre-assessment, the organization shall receive a report summarizing the organization's status regarding accreditation requirement and issues needing improvement. Holding a pre-assessment may improve the organization's chances of successfully complete a full assessment and can save the organization the expense of an unsuccessful assessment.

3.5.2 Preparations for an assessment

The ISRAC staff shall propose one or more assessor to the organization to perform the accreditation assessment, in each of the technologies submitted for accreditation. The assessors shall be chosen by the AB according to their expertise in the tests or calibrations performed by the organization. The organization has the right to reject an assessor if it recognizes a conflict of interests between itself and the assessor.

ISRAC assessors are expert scientist, advisors, industry members, academy members and members of the laboratory community. The assessors have a signed contract with ISRAC and are committed to confidentiality and upholding moral ethics.

The length of assessments ranges from one day up to several days.

ISRAC staff shall request copies of the organization's standard operating procedures and validation reports of methods, two months or more before the assessment date. The assessors may request additional documents for review, such as: equipment procedures, comparison test between employees, confirmations of participation in inter laboratory proficiency testing and additional documents required according to the relevant international standards, in order to prepare for the assessment.

The assessors shall review the quality manual, standard operating procedures and accompanying documents, prior to the assessment.

After reviewing the documents, the assessors may request the implementation of corrective actions regarding problems in the documents, before performing the assessment.

3.6 Accreditation Assessment

The purpose of an assessment is to determine whether an organization is in compliance with the requirements of the relevant international standard and the Israel Laboratory Accreditation Authority and has the professional ability to perform the activities included in the requested scope of accreditation see procedure number 2-623001: Planning and Performing the Assessment, on ISRAC website.

3.6.1 Accreditation assessment

An accreditation assessment planned and performed in the following order:

3.6.1.1 An opening meeting with the organization's representatives

3.6.1.2 A short tour with the organization's representatives

3.6.1.3 Interviews with the organization's employees

3.6.1.4 Assessment of selected activities/ tests/ calibrations

3.6.1.5 Assessment of the equipment and calibration documents (when relevant)

3.6.1.6 Review of the organization's quality system to ensure its full implementation and documentation.

3.6.1.7 A meeting summarizing the assessment's findings.

A lead assessor accompanied by technical assessors, experts on the areas submitted for accreditation, shall perform the accreditation assessment. The length of the assessment depends on the scope of accreditation requested and the number of facilities or branches of the organization. Each assessor from the team shall be accompanied by one of the CAB employees; the functions of the accompanying person are to confirm the assessor observation.

The assessment is performed by assessing a sample of the organization's activities and documents and therefore does not provide approval for the organization's entire scope.

During the assessment, the lead assessor preserves the right to stop the assessment at any given moment, with the approval of ISRAC's staff. This shall be done if a large number of non-conformities, that directly affect the quality of results, are found during the assessment or if the organization does not cooperate with the assessment team.

3.7 Non-Conformities

Non-conformities with the relevant standards and requirements may arise during the assessment.

Non-conformities shall be indicated against the relevant international standard, the method standard (if exists), the organization's procedures or ISRAC requirements (see section 2.2).

Non-conformities may reflect one of the following problems:

3.7.1 Inability of the organization to perform a calibration/ test or any other activity according to the accreditation requirements.

3.7.2 The organization's quality system does not comply with the standards requirements, is not sufficiently documented or isn't fully applicable.

3.7.3 The organization does not comply with any additional requirements presented by ISRAC or with specific requirements for a particular field.

3.7.4 The organization does not comply with its internal procedures.

Non-conformities classification is described in procedure number 2-623001: Planning and Performing the Assessment.

An assessment report will be send to the laboratory within 14 workdays from the assessment day. The organization is requested to respond to the assessment report, in a period of up to 20 workdays, detailing the corrective actions taken or that will be taken for identifying the non-conformities root causes in order to resolve the non-conformities. The organization shall set a feasible period for the implementation of the corrective actions and shall also submit any documentation proving their implementation, for example: calibration certificates, updated procedures, training documents etc. A CAB shall receive a response form ISRAC regarding its corrective actions.

ISRAC shall review whether all the corrective actions required for the correction of the non-conformity have been performed throughout the organization.

3.8 Decision on Accreditation

The recommendation on accreditation shall be discussed in the accreditation committee, as detailed in the procedure number 2-651001: The process of decision making regarding accreditation status of conformity assessment bodies, (see ISRAC website: www.israc.gov.il/publication/procedure). The accreditation committee will recommend to ISRAC General Manager to make the decision on accreditation.

3.9 Maintenance of Accreditation under ISRAC Surveillance

The organization's first accreditation shall be re-approved by re-accreditation assessments every two years, see procedure number 2-623001. In addition, as described in procedure 2-671001, Surveillance of Accredited Organizations, ISRAC may conduct a surveillance assessment (technical or management system) as a result of risk assessment, special or extraordinary assessment as a result of changes at the CAB organization, recommendation of the assessment committee etc. Accreditation certificate shall be issued to the period of two years after paying supervising fee. The annual fee is calculated as 12% from the accreditation cost. The CAB is charged right after the first accreditation granting and after re-accreditation for accreditation maintenance expenses.

In order to receive re-accreditation, the organization must successfully complete the re-assessment. If non-conformities are found during the re-assessment they shall be dealt with according to the description in the section regarding non-conformities.

An accreditation committee, as described in section 3.8, shall make the recommendation on re-accreditation.

3.10 ISRAC Requirements for Surveillance, Re-accreditation and Extension of the Accreditation Scope

The biannual surveillance agreement defines the responsibilities between ISRAC and the organization. As stated in the surveillance agreement, the organization must inform ISRAC beforehand and in writing on any significant change performed that can influence the organization's abilities to perform the test, calibration, and inspection activities. Significant changes include: changes in the organization's facilities, change in key personnel, updating standard operating procedures and inter laboratory proficiency testing results (when applicable). An example surveillance agreement can be seen on ISRAC website

About two months before the date of the surveillance assessment/ re-accreditation/ extension the scope of accreditation, the organization is requested to submit an updated copy of all CAB procedures as required in procedure number 1-000014: The preliminary request for accreditation/ re accreditation/ extension of the scope of accreditation/ surveillances document.

In addition, the organization shall receive regular updates on ISRAC's requirements, through the ISRAC newsletter and the ISRAC website, under "ISRAC directives". The organization must follow periodically the updates and adjust to them.

ISRAC expects its accredited bodies to periodically review and update their procedures if needed.

In order to request an extension of the accreditation scope, the organization must submit the information and documents as required in procedure number 1-000014: The preliminary request for accreditation/ re accreditation/ extension of the scope of accreditation/ surveillances document.

3.11 Test/ Calibration Report

The test/ calibration report shall include detailed information, as required by the relevant standard (for example section 7.8 in the ISO/IEC 17025 standard or section 5.8 in the ISO 15189 standard or section 7.4 in ISO/IEC 17020 standard) In cases where the organization has a written agreement with the client detailing the information required by the standard, a reference to this agreement, on the report, is sufficient. The results report may carry the ISRAC logo if at least one of the results reported in it are of tests performed under accreditation.

Accredited test report can be marked with the accreditation logo if at least one of the test results performed unfer accreditation. Results must be clearly marked in order to prevent misleading the clients as specified in procedure number 1-455001: Policy for the use of the ISRAC symbol (see ISRAC website: www.israc.gov.il /publication/procedure).

3.12 Suspension of Accreditation

Suspension means denying the organization the right to issue accredited reports in any of its fields of activity or in certain ones. The organization cannot provide accredited results in the suspended field of activity until the required corrective actions are performed as specified in procedure number 2-650001: Measures to be taken for suspension, termination, reduction, voluntary withdraw of accreditation as published on ISRAC website: www.israc.gov.il /publication/procedure**.**

During the suspension period the organization is still under ISRAC surveillance.

Accreditation shall be fully or partially suspended in the following cases:

3.12.1 Significant non-conformities with ISRAC requirements (systematic failure).

3.12.2 A significant breach of the surveillance agreement.

ISRAC shall send the organization a written announcement of the suspension of accreditation. The announcement shall include the reasons for suspension, the scope of suspension; explain the right for a hearing and the terms to the withdrawal the suspension, and the announcement's validity.

The period of suspension shall not exceed six months. In special cases an additional extension of three months will be granted. During the period of suspension, the organization may not mark its results as accredited. During this period all the necessary corrective actions should be implemented and ISRAC shall assess the results of their implementation.
The announcement on the cancellation of suspension shall be sent to the organization in a registered letter.
Both the act of suspension and its cancellation shall be published on ISRAC website.

3.13 Termination of Accreditation

Termination of accreditation means that the organization is no longer under ISRAC surveillance in the terminated field of activity.
The organization shall immediately cease marking its reports, in the terminated field, as accredited.
ISRAC shall fully or partially terminate accreditation for the following reasons:

- The reasons for suspension not being properly resolved.
- Significant breach of the condition for suspension.
- Normative problems in the organization.

ISRAC shall send the organization a written announcement, in registered mail, of the termination of accreditation. The announcement shall include the reasons for termination, the scope of termination; explain the right for a hearing and the requirements for cancelling the termination. The period of termination shall be at least six months long.
The act of termination and its cancelling shall be published on ISRAC website.

3.14 Hearing

If the organization does not agree with the General Manager's decision to suspend, terminate or not approve accreditation, it may submit a hearing request up to seven workdays after receiving the announcement. The hearing shall be discussed in the hearing committee, composed of an outside advisor, an ISRAC representative that did not took part in the previous discussions and the ISRAC legal advisor. The hearing discussion shall be held in the presence of a representative of the organization.
A written decision shall be sent to the organization.

For further details on a hearing see procedure number 2-651002: Procedure for the hearing and appeal committee (ISRAC website: www.israc.gov.il/publication/procedure).

4. THE COST OF ACCREDITATION

ISRAC is a nonprofit statutory organization, ISRAC charges its clients the accreditation expenses, including the cost of the services provided by it that are directly tied to the accreditation process, such as: document review, follow up on corrective actions, complaint handling, hearing etc.

The assessment rate is set according to the number of technologies submitted for accreditation by the organization. The technology structure is published on the ISRAC website. In addition, ISRAC charges an annual surveillance fee, for the sustenance activities held by ISRAC during the year, such as: training, surveillance of proficiency tests, publication of newsletters, international activities, etc.

The accreditation cost calculation breakdown can be found on ISRAC website/ISRAC and accreditation services/ISRAC price-list

5. ISRAC'S COMMITMENT TO CONDIENTIALITY AND ETHICS

5.1 Confidentiality

All the information received by ISRAC from applicants and accreditation bodies is defined as confidential information. All individuals involved in reviewing the submitted information sign a confidentiality agreement prior to receiving the information.

For an example of the confidentiality agreement see section 5.1.1.

Any information of this kind shall not be revealed unless written agreement is received from the organization, by ISRAC.

The obligation for confidentiality was decreed by law, in section 26 of the ISRAC to the law, 1997.

Section 25 of the Law declares that ISRAC employees are liable to be charged according to the law dealing with punishment of public employees (1997).

The "Punishment law" from 1997, in section 177 determines that any public servant must obey confidentiality regarding any information given to him as government employees. Any information regarding the identity of accredited organizations and their scope of accreditation is not considered confidential and is published on the ISRAC website.

If ISRAC staff is questioned regarding an organization in the process of accreditation, it shall answer that the organization is not accredited and shall neither deny nor confirm whether the organization is in the process. The ISRAC staff can confirm that an organization is in the process of accreditation only if it has received a written authorization from the organization to reveal information regarding its accreditation status.

If the organization chooses to announce that it has requested accreditation it can do it on its own responsibilty.

5.2 Rules of Conduct – Professional Ethics

ISRAC's policy decrees that any conflict of interest is to be avoided according to the professional ethic rules and the principles guiding ISRAC in -

ISO/IEC 17011; Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies.

ISRAC believes that accreditation services must be fair, objective and without any influence from private or personal motives of its personnel. Therefore all ISRAC employees sign a code of conduct.

6. GUIDANCE DOCUMENTS AND ISRAC POLICY

6.1 ISRAC has issued several not obligating guidance documents in order to explain its requirements for accreditation in addition to the relevant standards, which can be found on the ISRAC website. These documents include for example:

6.1.1 Document number G-119-02: Guidance document for writing a procedure (ISRAC website/ publications).

6.1.2 Document number G-119-03: Guidance document for the customers of calibration laboratories (ISRAC web site/ publications).

6.1.3 Document number G-119-04: Guidance/ checklist for computerized systems in laboratories and test facilities (ISRAC web site/ publications).

6.1.4 Document number G119-05: Guidance document for checkup kit evaluation (ISRAC web site/ publications).

Conclusion

ISRAC staff is at your service for help and additional explanations, training or help required. Please find on ISRAC website/ contact directory, contact details.

Wishing you success**,**

ISRAC staff

Appendix number 01

Accreditation fields of Israel Laboratory Accreditation Authority

Accreditation fields of Israel Laboratory Accreditation Authority

- This document is not an official translation. The original version is in Hebrew as Gazette no. 6397, 7193, 7522 in the Ministry of Justice website -

According to the Israel Laboratory Accreditation Authority Law, 1997 under approval of the Ministry of Economy and Industry, ISRAC's accreditation scope is as follows:

a) **Construction** – mechanical, chemical, physical and engineering tests -
   (1) Concrete;
   (2) Concrete products;
   (3) Cement;
   (4) Construction materials and products;
   (5) Concrete reinforcement steel;
   (6) Building systems (including sprinklers and smoke detectors for fire extinguishing);
   (7) Building envelope;
   (8) Building carpentry;

b) **Soil and paving -** mechanical, chemical and physical tests -
   (1) Foundations;
   (2) Asphalt and bentonite;

c) **Food, water and beverages** – chemical, biological and physical tests -
   (1) Processed and non-processed of food additives and dietary supplements, including medicinal herbs, spices and carriers;
   (2) Pesticides residues;
   (3) Contaminants residues;
   (4) Testing of work surfaces and storage containers;
   (5) Drinking water testing;
   (6) Recreational water testing;
   (7) Sewage and effluents testing, including contamination caused by the sewage;

d) **Cosmetics-** chemical, biological and physical tests;

e) **Fuels, oils and bitumen** -
   (1) Chemical, biological, physical and engineering tests;
   (2) Leak tests of tubing and immobile, portable or mobile tanks;

f) **Calibration** -
   (1) Mechanical, physical, chemical and electrical dimensions;

(2) Legal metrology of mechanical dimensions, physical dimensions, chemical dimensions, electrical dimensions, flow meters, liquids level indicators and weighing scales;

g) **Engineering details and non-destructive testing (NDT) -**

(1) Radiography;

(2) Ultrasonic;

(3) Magnetic particle;

(4) Dye penetrants;

(5) Eddy currents;

(6) Visual;

(7) Leak detection;

h) **Metals and non-metallic materials** - chemical, physical and engineering tests;

i) **Environmental** - chemical, biological, physical and engineering tests -

(1) All types of water;

(2) Sewage and effluents, surface water, sea water and beaches;

(3) Sludge soil, solid waste and surface runoff;

(4) Air, including ambient air, stacks and working environment;

(5) Asphalt and petroleum products;

j) **Electricity** – electrical, physical and engineering tests -

(1) Electromagnetic compatibility (EMC);

(2) Telephony;

(3) Product safety;

k) **Liquors in accordance with the liquor control act**;

l) **Health –** chemical, biological and physical tests -

(1) Medicine;

(2) Forensic medicine;

(3) Medical studies;

(4) Air, including ambient air, stacks and working environment;

(5) Noise;

(6) Agricultural products;

m) **Lifting devices**;

n) **Pressure tanks**;

o) **Computerized data**;

p) **Animal food -** biological, chemical and physical tests;

q) **Agriculture -** plants diseases diagnosis, biological, chemical and physical tests;

r) **Animal body fluids and tissues -** biological, chemical and physical tests;

s) **Medical preparation and medical devices -** biological, chemical, physical and engineering tests;

t) **Inter-laboratory proficiency testing (PT)**;

u) **Forensic samples** - biological, chemical, physical and engineering tests;

v) **Industrial products, including raw materials for industry** biological, chemical, physical and engineering tests;

w) **Industrial hygiene** - biological, chemical and physical tests.

x) **Evaluation of reference materials**;

y) **Testing in the field of transportation;**

z) **GLP testing facilities**;

aa) **GCLP testing facilities**