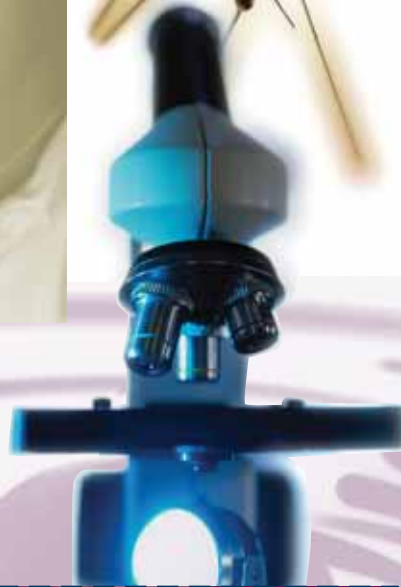
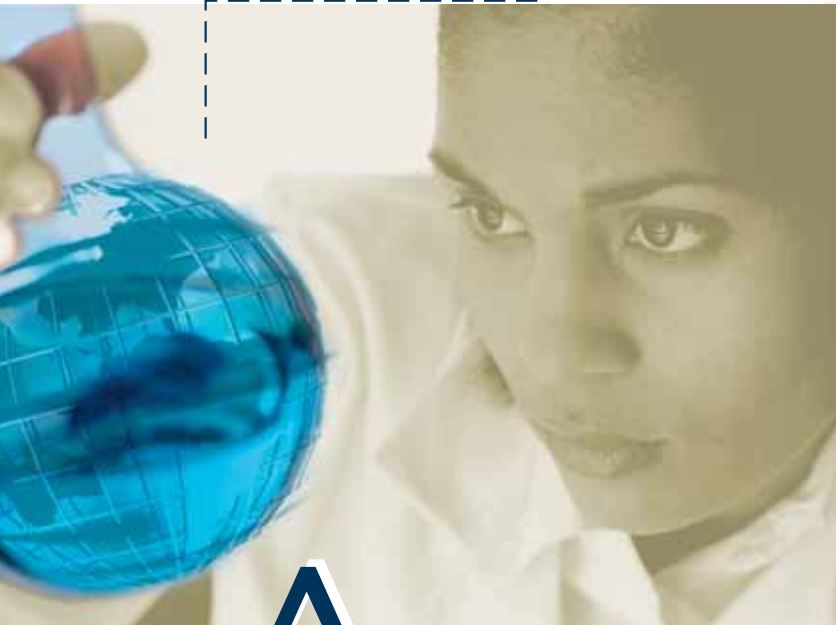




Ministry of Industry, Trade & Labor



ISRAC
Israel Laboratory Accreditation Authority



Annual Report

Year
2011



From the Chairman of ISRAC

ISRAC was established about 15 years ago as a highly important national facility. There are hundreds of laboratories dispersed throughout the country, providing analytical services in medical, engineering, chemical, structural, and agricultural areas. Israel's health, security and economic strength depend on the reliability of these analytical services. In addition, the available analytical services are important both for Israeli society to have confidence in the quality of products that we produce here, and for our export products to be well accepted overseas. In our country, ISRAC is the only formal national tool available for maintaining the high standards of all the analytical laboratories, standards that are adopted by the most advanced countries throughout the world.

Earlier this year, Mrs. Ety Feller started her position as the general director (CEO) of ISRAC. With her assuming of the position, began a process of change which included preparations for the changing of the inspection system, addition of professional workshops and changing the organizational structure to streamline work processes in ISRAC.

The Authority provides current accreditation to 165 laboratories in different testing areas. 17 employees operate approximately 80 assessors who, on a current basis, supervise all the laboratories under our umbrella and endeavor to ensure that the accreditation that we provide them has a sound basis. 2011 can be considered as a very successful and prolific year for ISRAC. 18 new organizations were accredited and 16 workshops were organized for various organizations. In addition, employees of ISRAC participated in international activity, as Israel's relationship with parallel international organizations is extremely important to ISRAC employees.

ISRAC has a formal agreement with the International Laboratory Accreditation Cooperation (ILAC), and in 11.2011 ISRAC was accepted as a member of the European Accreditation (EA) organization. Continuous activity of employees of ISRAC in the framework of these organisations constitutes an important phase in building confidence in the work of laboratories in Israel and recognition of their results in the member countries of these organisations. ISRAC conforms to both the standards of ISO/IEC 17011 and the standards of OECD. I want to express my highest appreciation to the excellent preparation work that was carried out by the staff of ISRAC.

I should also acknowledge with great satisfaction the excellent relationship that we have with all the formal Israeli governmental bodies with whom we work, including the Ministries of Finance, Agriculture, Industry and Commerce, Environment and Law.

Over the years ISRAC has demonstrated a very balanced and responsible operation from the financial point of view. The annual reports always reflected a balanced and reasonable budget. Consequently, we benefit from the cooperation and full confidence of all the governmental bodies with whom we work.

It should also be mentioned that during 2011 some re-organization took place among ISRAC's Board of Directors. Those members who concluded their service either renewed their term or were replaced by new members. Hence, ISRAC continues to demonstrate itself as a dynamic organization.

This letter is written just before our national holiday of independence, namely, Chag Pesach. The parameters that ensure our independence include hard work at high standards of reliability and honesty. ISRAC can definitely be considered as a body that works at high standards. I look forward to ISRAC's continuing excellent and prolific contribution to our society.

In conclusion, I want to thank my colleagues at ISRAC for their dedication and devotion towards maintaining a high standard of work, and I wish you all everything of the best, good health, and happiness.

Sincerely yours,

Prof. Doron Aurbach

From the General Manager

In the first quarter of 2011 I was appointed General Manager therefore, naturally, this year was characterized by changes. Firstly, a General Manager of ISRAC was appointed after 3 years where one was absent. This appointment, together with changes in the organizational structure which are currently being completed, will enable the ISRAC staff to provide effective service to its customers.

The ISRAC staff is extending its collaboration with various regulators. This collaboration provides the regulators with a tool to monitor the developments in their fields without being a burden upon their ongoing activities and their annual budget and especially to those regulators using accreditation services as part of the approval or recognition requirements.

During the year, in light of the European organisation's policy change to accrediting laboratories and the findings of the EA (European Accreditation) recognition assessment, ISRAC began the necessary change in the inspection method and, throughout the year, a technical assessor joined every inspection assessment, at no additional fee to the organisation.

At the EA General Assembly Conference in November 2011, the representatives of the EA member organisations agreed to confirm, for the first time, partnership to 12 states, with Israel among them – the Israel Laboratory Accreditation Authority, to be members at a partner status in the EA beginning 23rd November 2011.

The Israel Laboratory Accreditation Authority ISRAC was appointed by the state of Israel, in the subject of inspection according to OECD-GLP principles, hosted the biannual inspector course of the World Organization for Cooperation and Economic Development, the OECD. The Israel Laboratory Accreditation Authority was accepted as a full member in the work group in the field of OECD-GLP. In 2004 and in 2006 it was decided to hold the inspector course in Israel. 63 inspectors from 31 member states including China, Turkey, Russia and Australia, participated in the course.

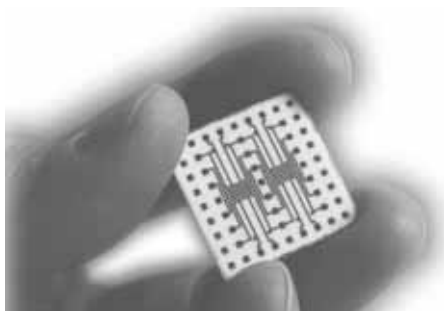
The Law of the Authority is still in the process of being updated and we hope that the coming year will bring "news". The updating of the Law is very significant to the widening of ISRAC's activities to fields which up until now, ISRAC has precluded from engaging in. On the one hand, regulators seek to accredit areas of inspection and to certify management systems, and on the other hand, those involved in the work – the assessors and the inspectors needed for this accreditation are required to receive it from foreign and expensive districts.

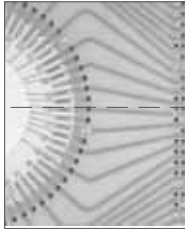
During the year, ISRAC employees devoted their efforts to building a diverse training program for employees of accredited bodies. For technical assessors, professional seminars were planned aiming to explain the accreditation requirements on a professional level and not only the quality management of the organisation. I wish to thank all the employees of ISRAC, thank you for the effort and willingness to work tirelessly in the various fields of activity of ISRAC, in promoting the mission of ISRAC "promoting quality and professional competence of calibration bodies/assessing in harmony with the world for the state and its citizens".

To the various regulators who use accreditation as part of their trusted implementation processes, to the interested parties and to our public consumers who put their trust in the activities of ISRAC.

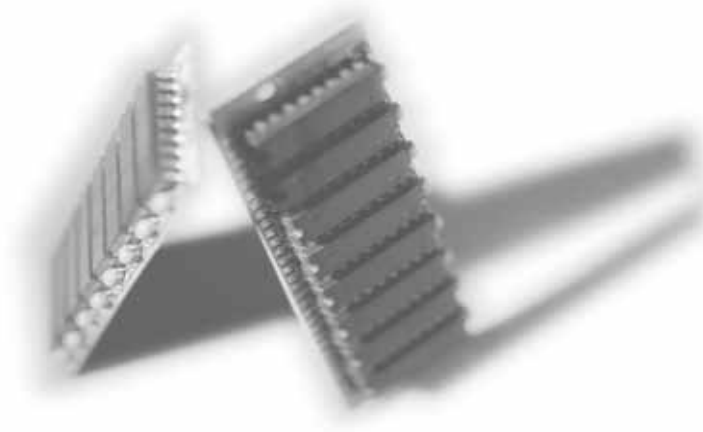
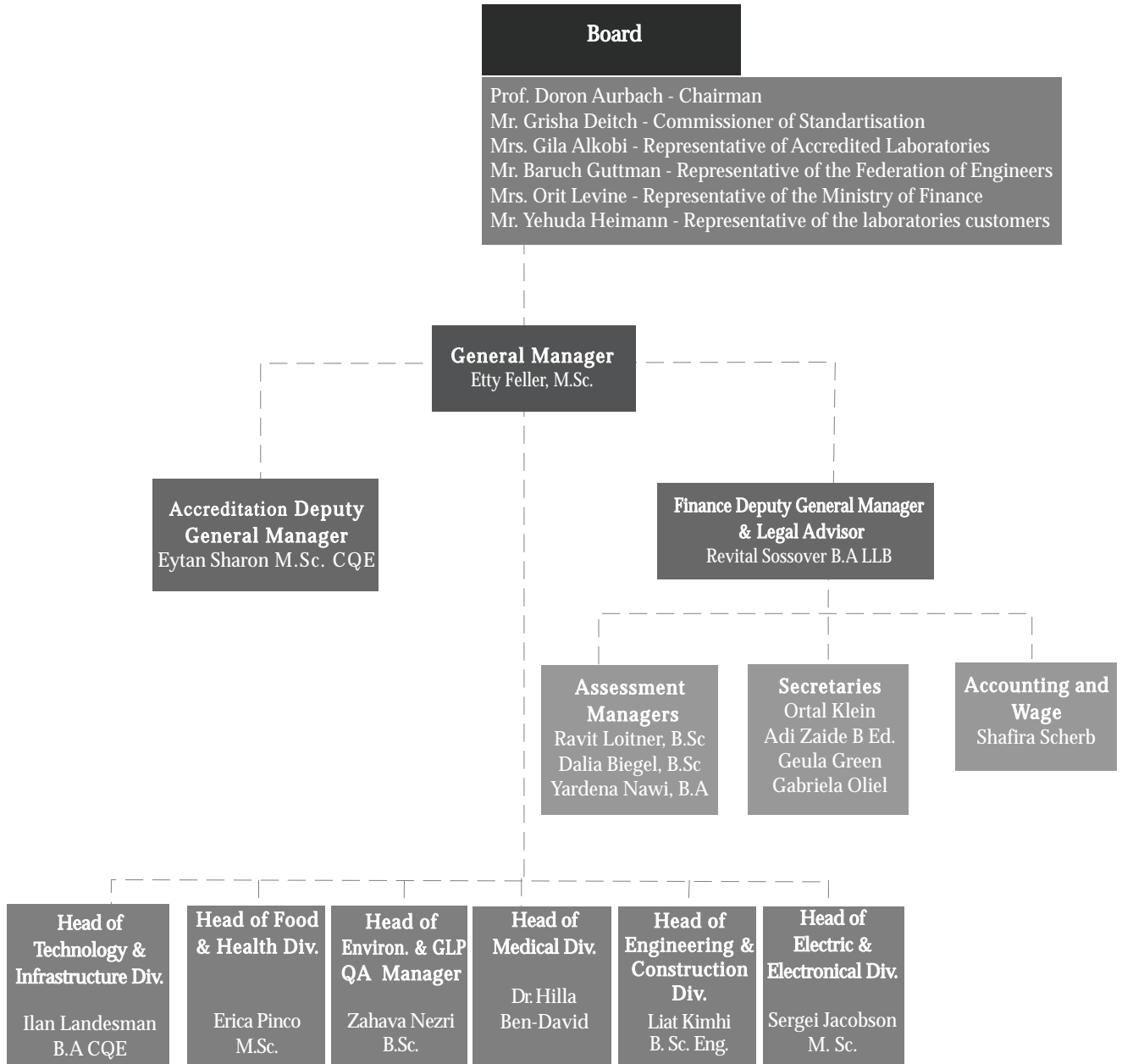
Etty Feller

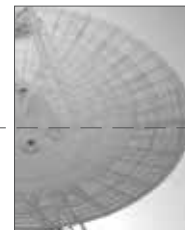
General Manager





Organization chart





About ISRAC and ways of establishing contractual relations

The early 1990s was characterized by increasing awareness in Israel and around the world of the importance of ensuring product quality and compliance with national or international standards. These standards are intended mainly to ensure that products bearing standard emblems are of adequate quality, and that their use would not pose risks to health, safety or the environment. In the international trading system, products are required to meet standards or client's requirements. In order for the results of tests performed at laboratories in one country to be recognized in other countries, an international accreditation system is required, accrediting laboratories according to their capacity to perform tests at the required level. Such recognition may be extremely helpful in promoting export, particularly by helping exporters overcome non-tariff barriers in the target countries resulting from limited standardization. The accreditation bodies in the industrialized nations have formed a number of blocks. The most important of which are EA - European Union countries, and APLAC - the Asian and Pacific countries. Each block sets the accreditation policy for the affiliated accrediting bodies, and ensures their compliance with international standards and other requirements as determined. These organizations are part of ILAC (International Laboratory Accreditation Cooperation), whose function is to coordinate global accreditation policy and promote harmonization between the blocks. Israel has a mutual agreement with EA and is a full member of ILAC.

A number of laws and regulations in Israel empower the authorities and Government Ministries to grant legal force to the tests performed at laboratories that have received their recognition. For example, the Standards Law, (1953) empowers the official of the Ministry of Industry and Trade responsible for standardization to approve a laboratory as an "approved laboratory". The significance of the approval is that a test certificate provided by such a laboratory constitutes evidence of the compliance of a product with the Israeli standard. The approval of a laboratory's status requires that the tests be performed according to clear, uniform and internationally accepted rules.

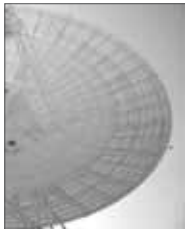
In 1992, in preparation for the establishment of an accreditation system in Israel, meeting international standards and gaining international recognition, the Minister of Industry and Trade appointed a committee to examine the issue of the accreditation of laboratories.

In August of the same year, the committee presented its recommendations, stating that there was an urgent need to establish a national system for the accreditation of laboratories. Following this, the Minister decided in 1993 to establish the Israel Laboratory Accreditation Authority (ISRAC); an advisory committee was established and charged with developing the necessary infrastructure for ISRAC's activities and with initiating the process of accrediting laboratories. In 1995 the committee began to accredit laboratories. The committee's work led, in April 1997, to legislate the Israel Laboratory Accreditation Authority Law, 1997 (hereinafter "the Law"). Among other aspects, the Law defines the following functions and authorities for ISRAC:

- To determine, with the Minister's authorization, the areas of accreditation in which it is active.
- To define requirements for the accreditation of measurement, calibration and test laboratories.
- To ensure that laboratories meet the requirements for accreditation and, accordingly, to continue or withdraw the accreditation of laboratories.
- To serve as the exclusive representative of the state in all matters relating to mutual recognition of the accreditation systems of other countries or of international organizations.
- To initiate supplementary activities to the accreditation of laboratories, such as training, publicity and information.

What is the Accreditation of a Laboratory?

The accreditation of a laboratory implies official recognition of that laboratory's professional capability and competence to perform specific types of tests, measurements and calibrations. Accreditation is



available for all types of calibration and test laboratories, whether these are part of a factory, or belong to the public or private sector. Accreditation enables consumers wishing to test or calibrate a product, substance or instrument to find a reliable service for testing or calibration that meets their needs. It also enables the laboratory to evaluate whether it is performing its work properly and in accordance with international standards.

Important! Accreditation of a laboratory provides formal recognition of its professional capability, thus constituting a means for enabling clients and major consumers in the economy, such as the enforcement authorities, to assure that they receive a reliable and qualitative service for tests, measurements and calibrations.

ISRAC's International Activities: Outline and Ramifications

Accreditation

ISRAC is a member of ILAC (International Laboratory Accreditation Cooperation). As such it is committed, like all other members, to act in accordance with the international standard for laboratory accreditation bodies: ISO/IEC 17011 – Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies.

During the year 2001 ISRAC was recognised by ILAC and by the EA (European regional organization). ISRAC has signed the ILAC mutual recognition arrangement (MRA).

The MRA provides recognition by the accreditation bodies of 37 countries that have already signed MRAs for any test or calibration performed by a laboratory accredited by ISRAC.

ISRAC's employees play an active role in both ILAC and the EA's professional committees. This action exposes Israel and the infrastructure of its laboratories to all the international economic organizations and will facilitate the industry to gain confidence in the analysis results that its products undergo.

GLP

ISRAC is the official representative of the state of Israel for recognition of research facilities for Good Laboratory Practice (GLP). The State of Israel has signed an MRA with the European Union and a Memorandum of Understanding (MoU) with the EPA. This MoU will become an MRA following a visit of a delegation from the EPA to the recognized laboratories and to ISRAC's offices. At the end of last year ISRAC was invited as an observer to a committee discussing these issues at the OECD.

Israeli research facilities interested in participating in pre-clinical experiments in the fields of pharmaceuticals, cosmetics, pesticides, food additives and environmental toxicity are required to receive recognition that they operate in accordance to the directives of the OECD, EPA or FDA. As of the end of 2011 fifteen research facilities have been recognized for GLP.

ISRAC's Commitments

The entire staff of ISRAC, including its managers, assessors and consultants, sign a confidentiality agreement to protect the confidentiality of information belonging to ISRAC clients. In addition, ISRAC employees are committed to a code of conduct - objectivity, transparency and avoiding conflict of interests.

ISRAC's Fields of Activities

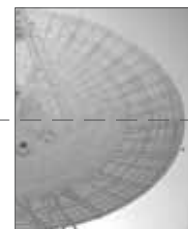
Laboratory accreditation may be provided for any type of properly documented test, measurement or calibration. At present, ISRAC accredits for the following types of tests / calibrations:

Types of tests

- Destructive tests
 - Chemical
 - Physical
 - Biological / microbiological
- Non-destructive tests

Types of calibrations

- Mechanical sizes
- Electrical sizes
- Optical sizes
- Physical sizes



Accreditation is provided in the following fields:

- Construction
- Paving and soil
- Food and Water
- Cosmetics
- Fuel and bitumens
- Calibration
- Non-destructive tests (NDT)
- Information Technology
- Metals and Semi-metals
- Environment
- Electricity
- Alcoholic beverages
- Health (Medical laboratories, Forensic and Medical research)
- Lifting Devices
- Pressure vessels
- Animal Food
- Agriculture: Detection of damage to plants
- Medical Devices

ISRAC is working to develop additional fields of accreditation, in order to meet the demands of the Israeli market and specific clients.

ISRAC is active in the recognition of laboratory facilities operating in accordance with the GLP directives of the FDA, EPA, and OECD. Recognition for GLP is provided in the following fields:

- Cosmetics
- Industrial chemicals
- Pharmaceuticals/medicinal products
- Food Additives
- Animal food additives
- Pesticides

Requirements of Accredited Laboratories

ISRAC's requirements and rules for the accreditation of laboratories were based on the international standard ISO/IEC 17025: "General requirements for the competence for testing and calibration laboratories." Medical laboratories are accredited according to a specific standard, ISO 15189, which is based on the ISO/IEC 17025. In addition, specific criteria for various fields complete the general criteria.

In practical terms, ISRAC ascertains the following in accrediting a laboratory:

- Laboratory facilities, professional capability and systems are appropriate for performing the tests and calibrations detailed in the scope of accreditation.
- The quality system of the laboratory meets all requirements of the relevant standard ISO/IEC 17025 or ISO 15189 and is properly documented and fully implemented.
- The laboratory meets ISRAC's complementary criteria for the accreditation of laboratories in areas relating to its scope of accreditation, relating primarily to requirements in the Israeli law or reality, or constituting an extension or explanation of generalized statements in the standard.

Accreditation for a laboratory is not generalized, but granted for specific methods of testing, measuring and calibration, as detailed on ISRAC's Internet site, www.israc.gov.il.

Our Recommendations to Laboratory Service Consumers

ISRAC recommends that those who use the results of measurements, tests or calibration ascertain which laboratories are accredited and their scope of accreditation. The scope of accreditation defines the specific types of test or calibration capabilities for which the laboratory has received accreditation.



The Added Value for the Accredited Laboratory

An accredited laboratory is permitted to mention its accreditation on its documents and test certificates, relating to the tests for which it is accredited. Accreditation is performed in accordance with international rules recognized by members of ILAC, including European nations, United States, Japan, Australia, India, China and additional countries around the world.

The quality system provides a tool for ensuring that the laboratory will monitor its activities and draw conclusions in order to ensure constant improvement. Accreditation is recognized by the European governmental authorities and, in many cases, provides a basis for their recognition. Laboratories that are managed in accordance with the rules of accreditation improve the efficiency of work processes, including: proper first-time implementation, reducing the number of repeat testing; preventative maintenance of equipment, saving unnecessary investments in repairs and acquisitions, and so on.

How to Contact ISRAC:

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Phone: 03-9702413, Fax: 03-9702413, E-mail: israc@israc.gov.il, Website: www.israc.gov.il

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Deputy General Manager	Eytan Sharon	M.Sc, C.Q.E	03-9702727(219)	eytans@israc.gov.il
Finance Deputy General Manager & Legal Advisor	Revital Sossover	ECO, B.A., L.L.B	03-9702727(206)	revitals@israc.gov.il
Quality Assurance Manager	Muriel Cohen	Ph.D, M.B.A	03-9702727(237)	murielc@israc.gov.il
Head of Electric & Electronical Div.	Sergei Jacobson	M.Sc.	03-9702727(205)	sergeij@israc.gov.il
Head of Technology & Infrastructure Div.	Ilan Landesman	B.A C.Q.E	03-9702727(202)	ilanl@israc.gov.il
Head of Engineering & Construction Div.	Liat Kimhi	B.Sc. Eng.	03-9702727(204)	liatk@israc.gov.il
Head of Food & Health Div.	Erica Pinco	M.Sc.	03-9702727(208)	erica@israc.gov.il
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Secretary	Ortal Klein		03-9702727(200)	ortals@israc.gov.il
Secretary	Adi Zaide	B.Ed	03-9702727(207)	adiz@israc.gov.il
Secretary	Gabriela Oliel		03-9702727(207)	goliel@israc.gov.il

*The above information is correct for the year 2011. Updated information can be found on our website: www.israc.gov.il



Main activities during 2011

Last year we set ourselves the following goals:

- Approval of the revised law
- Enhancing the relations with all government regulators
- Cooperation with international accreditation and standard organizations
- Increasing the number of accredited laboratories and the technologies they are accredited for.
- Enhancing the cooperation with the Industry Association, Consumer laboratories, Export Institution and Chamber of Commerce.

The goals that were completely under our control have been fully achieved. Regrettably, we did not reach this success concerning other goals that were dependent on cooperation with others.

Approval of the revision of ISRAC's law

This is an ongoing mission.

The political reality did not allow for the passing of the amended law. However, the legal department in the Ministry of Industry Commerce and Employment had issued a detailed document pointing out the need of the state in more tools and means to enhance the enforcement.

Following this document there were many meetings between our legal department and the legal departments of the Ministry of Industry Trade and Commerce and the Ministry of Legal Affairs. The revision of ISRAC's law will facilitate, among other things, the implementation of the new regulations in the construction field. A draft was decided upon which will be distributed for comments from the Government Ministries.

Accreditation of new laboratories

16 new laboratories were accredited in 2011.

The total number of accredited organizations at the end of 2011 reached 161, compared to 147 at the end of 2010.

No significant breakthrough in the number of accredited medical laboratories happened in spite of the fact that this area has great potential.

Cooperation with international accreditation and standardization organizations

ISRAC has active representatives in the following organizations:

- EA – European Accreditation
- ILAC – International Laboratory Accreditation Cooperation
- OECD – Organization for Economic co-operation and Development in The GLP (Good Laboratory Practice) area.

The world financial crisis

ISRAC was not affected by the economic crisis in 2011.



Governmental office	Laboratory services	Requires accreditation	Ministerial laboratories are accredited
Health	Water and food	✓	✓
	Clinical labs	-	✓ (partial)
Agriculture	Pesticides,	-	✓
	Remnants of pesticides (required for export)	✓	✓
Defense	All fields	✓	No labs
Trade, Labour & Industry	Commissioner of standards (official standards)	✓	No labs
	Radiation	-	No labs
Trade, Labour & Industry	Industrial hygiene	✓	✓
	Noise	✓	✓
Environmental Protection	Radiation	In process	No labs
	Soil, wastewater, fuels	Partial	No labs
	Air Quality	✓	No labs
	Pesticides	In process	No labs
Internal Affairs	Population of buildings (form 4)	✓ (Except SII)	No labs
	Construction	✓ (Except SII)	No labs
Infrastructure	Fuel	✓	No labs
	Water meters	✓	No labs
	Electricity testing	-	-
	Water Quality	-	✓
Transportation	Vehicles	-	No labs
	Traffic control devices	✓	No labs
Housing and Construction	Construction	✓ (Except SII)	No labs
Homeland Security	Forensic Science	-	✓
	Traffic Police	Beginning the process	No labs



►►► The main activities planned for the year 2011

- Approval of the ISRAC law.
- Increasing the number of accredited organizations and increasing the scope of accreditation of the existing accredited organizations.
- Organizing professional courses to improve quality and professionalism in accredited organizations
- Developing new areas of accreditation and new testing methods in existing areas
- Upgrading ISRAC's website
- Completion of implementing the change in the surveillance assessments policy of accredited organizations as a part of the mutual recognition requirements between ISRAC and EA and ILAC
- Broadening the cooperation between ISRAC and regulators in all Government Ministries, Manufacturers Association, Consumer Organizations, the Israel Export Institute, the Standards Institution of Israel and the Chambers of Commerce
- Cooperation with international accreditation and standardization organizations



Annual Report 2011

Budget for 2011 and 2012

Budget for 2010 and 2011

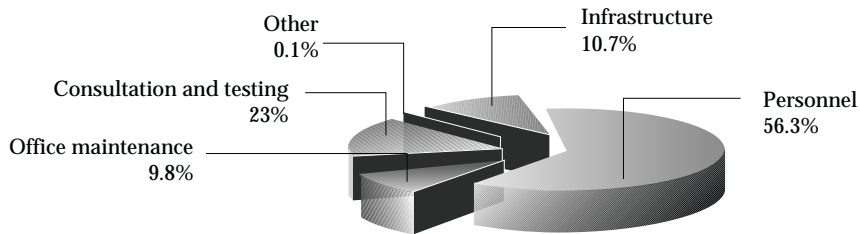
	2011 budget	2012 budget	Nominal Change
	NIS 000's	NIS 000's	%
Expenditure			
Regular operations	6,300.0	6,045.1	-4.0
Development	3,297.3	3,178.8	-3.6
Total Expenditure	9,597.2	9,223.9	-3.9
Income from Operations			
Accreditation and surveillance	4,584.0	5,008.7	9.3
Training and GLP inspections	200.0	195.0	-2.5
Total Income from Operations	4,784.0	5,203.7	8.8
Income from Funding			
Funding of development - State budget	3,500.0	3,178.8	-9.2
Regular funding - State budget	0.0	0.0	0.0
Preceding Year's Surplus	1,113.2	870.2	-21.8
Income from interest	200.0	150.0	-25.5
Total Income from Funding	4,813.2	4,198.9	-12.8
Total Income	9,597.2	9,402.6	-2.0

Expenditure

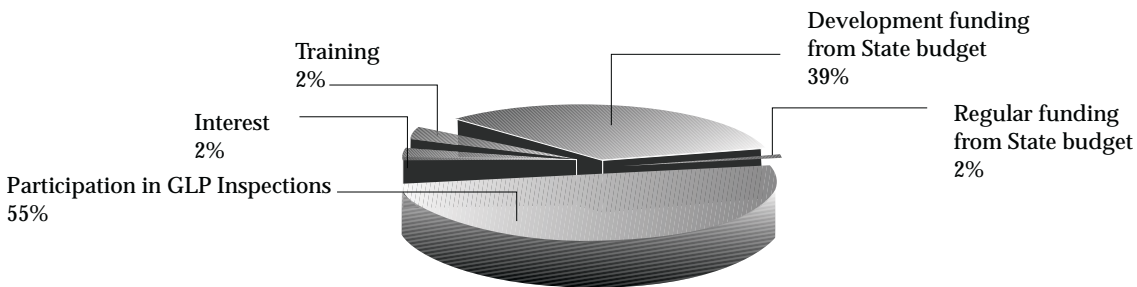
		2011 budget	2012 budget	Nominal Change
		NIS 000's	NIS 000's	%
Expenditure				
1.0	Personnel	5,407.7	5,997.4	10.9
2.0	Consultation and testing	2,211.2	1,196.9	-45.9
3.0	Office maintenance	939.9	930.1	-1.0
4.0	Other	10.0	10.0	0.0
	Total operating expenditure	8,568.8	8,134.5	-5.1
	Development element	-2,694.7	-2,547.3	-5.4
	Total regular operations	5,874.1	5,587.2	-4.9
5.0	Infrastructure	1,028.5	1,089.4	5.9
	Development components	2,694.7	2,547.3	-5.4
	Total development	3,723.2	3,636.6	-2.2
	Total	9,597.4	9,223.9	-3.9



Breakdown of Expenditure in 2011



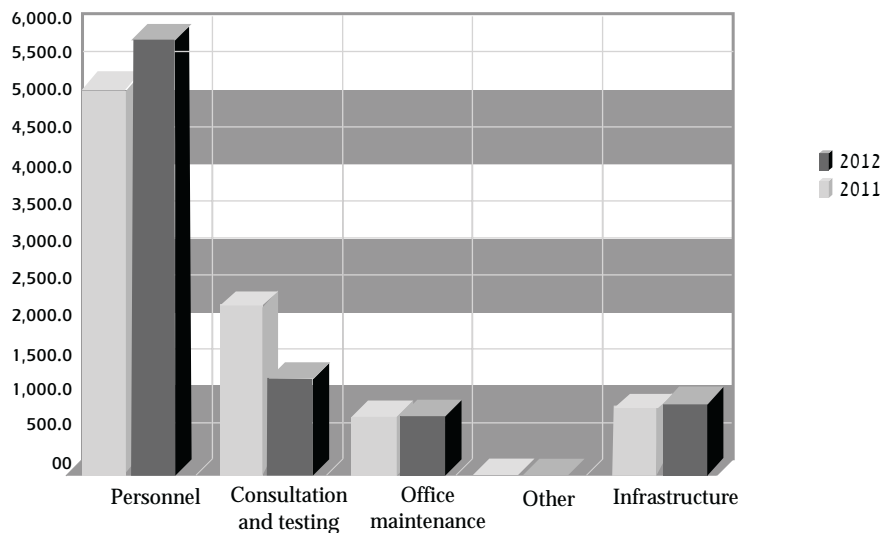
Breakdown of Income in 2011



As of January 2012, 147 laboratories have received accreditation, and 14 research facilities received recognition to GLP. 13 laboratories are in the process of accreditation.

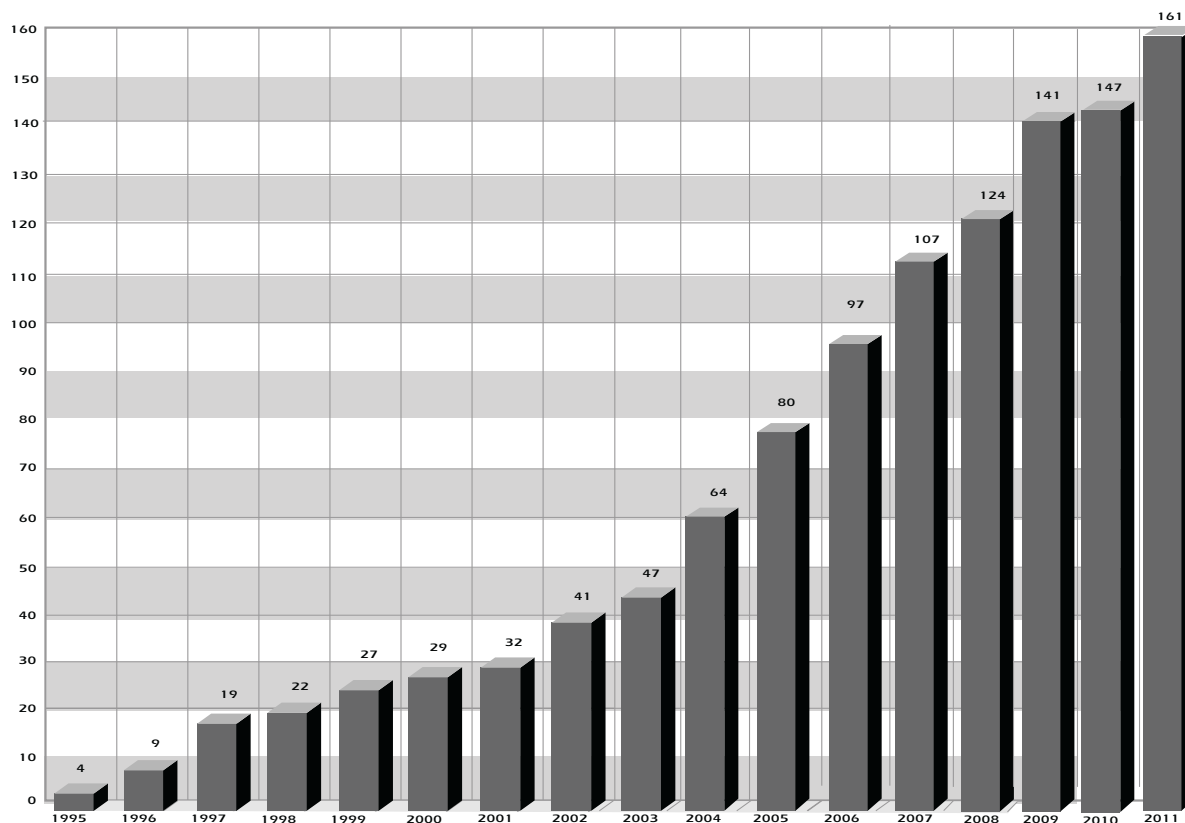
Department	No. of accredited labs.	No. of labs. in the process of accreditation
Engineering	23	3
Health	27	2
Environment	18	0
Medical	19	1
Electric & Electronics	29	5
Infrastructure	31	1
GLP (accreditation)	14	1

Forecast of Expenditure in the 2012 Budget in Comparison with the 2011 Budget:





The following chart shows the growth in the number of accredited laboratories according to ISRAC's years of operation (including the advisory committee that preceded ISRAC)



Freedom of information and transparency in ISRAC

ISRAC is a national public organization established by law. As such, ISRAC operates in accordance with Israel's Freedom of Information Law. ISRAC makes every effort to publicize and open its activities for the public, including clients, regulators, interested bodies and others.

In accordance with the law, ISRAC publishes its activities through its annual report.

ISRAC's quality manual (for accreditation and GLP) and some of its policies are available on ISRAC's website - www.israc.gov.il. This site also provides the list of laboratories accredited by ISRAC, including their scope of accreditation, as well as ISRAC guidelines and extensive additional information. ISRAC's website is bilingual (Hebrew & English).

Every four months, ISRAC publishes a newsletter, "Reshuton", providing news about ISRAC and accreditation, abstracts of some of the procedures, obligatory requirements, professional articles, information about training and seminars, updated lists of accredited laboratories and their scope of accreditation, etc. The "Reshuton" is distributed to about 2,500 readers, and is also available to participants in seminars and, upon request, to any interested parties. The "Reshuton" is also published on the web site.

ISRAC maintains ongoing dialogue with its clients through meetings, courses and feedback questionnaires. ISRAC publishes information about itself and the accreditation process, which is available free of charge and on demand. This booklet provides general explanations about ISRAC's work and operations and details on the accreditation process.

In addition to the above, the administrative guidelines binding ISRAC, as well as other information (subject to ISRAC's confidentiality restrictions), may be read by any citizen at the ISRAC offices daily between 8:30 AM - 5 PM, by prior arrangement.