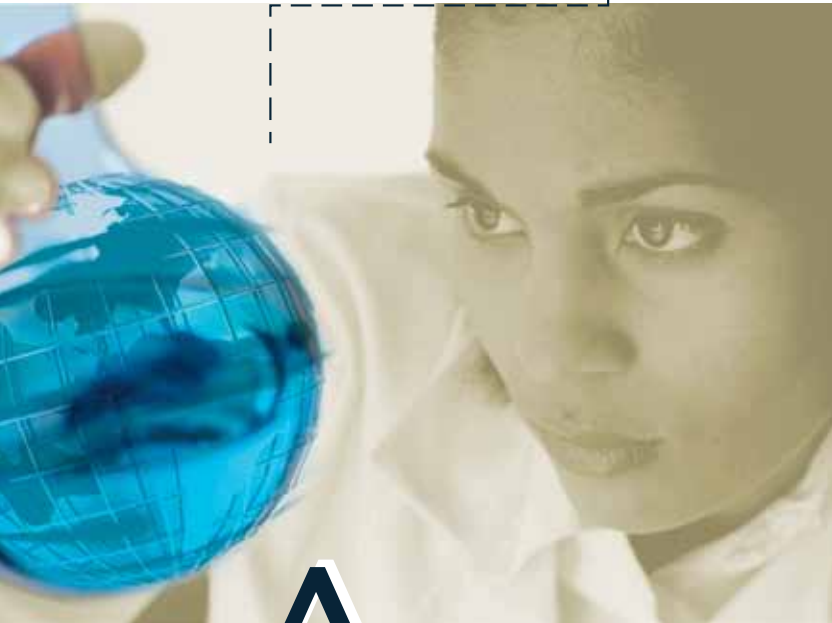




Ministry of Industry, Trade & Labor



ISRAC
Israel Laboratory Accreditation Authority



Annual Report

Year

2012



Annual Report 2012

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From the Chairman of ISRAC

The year of 2012 marked many challenges and achievements for all of us, including development of new accreditation areas, improving infrastructure, maintaining our good relationship with all our customers despite changes in the economy and the markets in Israel and abroad, absorbing new excellent man-power, applying internal structural changes, in order to further improve our services, strengthening collaboration with regulators with which we work and more.

ISRAC was established about 16 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. In the previous year, Mrs. Ety Feller started her position as the General Manager (CEO) of ISRAC. During 2012, Mrs. Feller led ISRAC very successfully, crystallizing around her highly dedicated, diligent and responsible team. The preparation for the changes required to fully meet the standards of OECD countries (especially those of the parallel European accreditation organizations) was intensified and in fact was competed very well during 2012.

The Authority provides current accreditation to 168 laboratories in different testing areas. 18 employees operate approximately 100 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. 2012 can be considered as a very successful and prolific year for ISRAC. During this year we applied, for the first time, the new inspecting and accreditation system, according to which accreditation is provided for each organization every two years (in this way meeting the highest international standards). 30 organizations broadened their activities to new areas of accreditation under ISRAC's umbrella during 2012. 90 organizations were examined during 2012. 7 new organizations joined the list of happy customers. The authority carried out special examinations in which the capability and the professional performance of several laboratories were compared in the following areas: atmospheric contaminants, noise analysis, water purity and NDT tests. ISRAC is well connected to international activities in many fields of accreditation. Employees of the Authority participated in international conferences.

ISRAC has a formal agreement with the International Laboratory Accreditation Cooperation (ILAC) and during 2011 ISRAC was accepted as a member of the European Accreditation (EA) organization. The relationship with this important European organization was strengthened during 2012, as in the general assembly of ILAC, in October 2012, the ILAC delegates agreed to broaden the recognition of the European organization in the "inspection" authorization of ISRAC. It can be said that the continuous activity of employees of ISRAC in the framework of the international

organizations, constitutes an important process of 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-GLP, according to the principles of OECD-GLP. In this framework, a representative of ISRAC participated this year in an official OECD inspection of accreditation authorities in Japan. I express my highest appreciation to these efforts of the staff of ISRAC to put Israel on the international map of high accreditation standards.

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. In terms of legislation activity: we are awaiting the expected updating and upgrading of the "Israel Accreditation Authority Law". A completion of this legislation will enable ISRAC to broaden its areas of activity in ways that will be very beneficial for Israel industry, services, health and economy.

The official list of ISRAC activities was updated during 2012. In fact, ISRAC started with a harmonization activity that intends to integrate all the accreditation activity in the state of Israel under an umbrella of well-defined standards, norms and the highest level of reliability. This process started during 2012 and is expected to be completed during 2014.

ISRAC staff was very active during 2012 in tutorial and teaching programs. During last year the Authority planned to provide about 25 days of instruction meetings in different areas. Due to the high demand, the actual number of tutorial and instruction days was 33.

Since ISRAC is a dynamic organization, there were some important changes in its personnel: Dr. Sigalit Mudachi (previously the quality manager of the laboratories of Hadassah Hospital in Jerusalem) was nominated as the Deputy Manager of ISRAC (starting July 2012). Avi Kivity started his work as the head of the engineering department. In turn, Dr. Hila Ben-David and Liat Kimchi finished their employment in the Authority after long years of highly prolific and highly appreciated work. Meidar Bar-Gergi and Shlomit Dokar were successfully absorbed as secretaries.

This letter is written after we celebrated 65 years of independence for the State of Israel. 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 very hard to keep standards of laboratories in this state at the highest level of reliability and professional output. 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 the best, good health, and happiness.

Sincerely yours,
Prof. Doron Aurbach



From the General Manager

The year 2012 summoned many challenges for us all. Challenges which combined: developing areas of accreditation, maintaining accredited organisations in light of the economic turmoil and improving infrastructure. Internally – implementing the changes in the organizational structure and absorption of new employees, and externally – enhancing customer service.

The ISRAC staff extended 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. New areas of accreditation in 2012: plant diseases, fuel vapor recovery and air monitoring.

During the year, the new inspection method was implemented, according to which, re-accreditation is given every two years according to international requirements.

At the ILAC General Assembly Conference in October 2012, the representatives of the member organisations agreed to confirm expanding the recognition of the Israel Laboratory Accreditation Authority for inspection.

The Israel Laboratory Accreditation Authority was appointed by the State of Israel, in the subject of inspection according to OECD-GLP principles. ISRAC was accepted as a full member in the work group in the field of OECD-GLP in 2004.

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.

In March 2012, the records dealing with the areas of activity of ISRAC were updated. These records enable accreditation, according to the Law of the Authority, of a wide range of sampling, testing and calibrating activities.

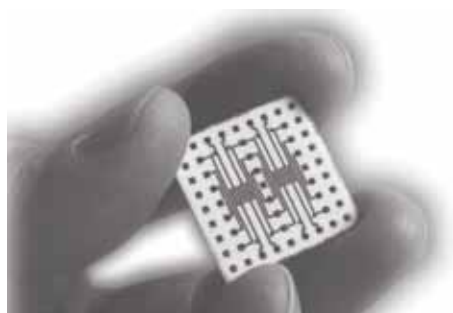
During the year, ISRAC employees devoted their efforts to building a diverse training program for employees of accredited bodies. For technical assessors, professional seminars were planned aiming to explain the accreditation requirements on a professional level and not only the quality management of the organisation. This program has been very successful. The number of participants was large and there was great interest in the professional training issues.

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 / testing bodies 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.

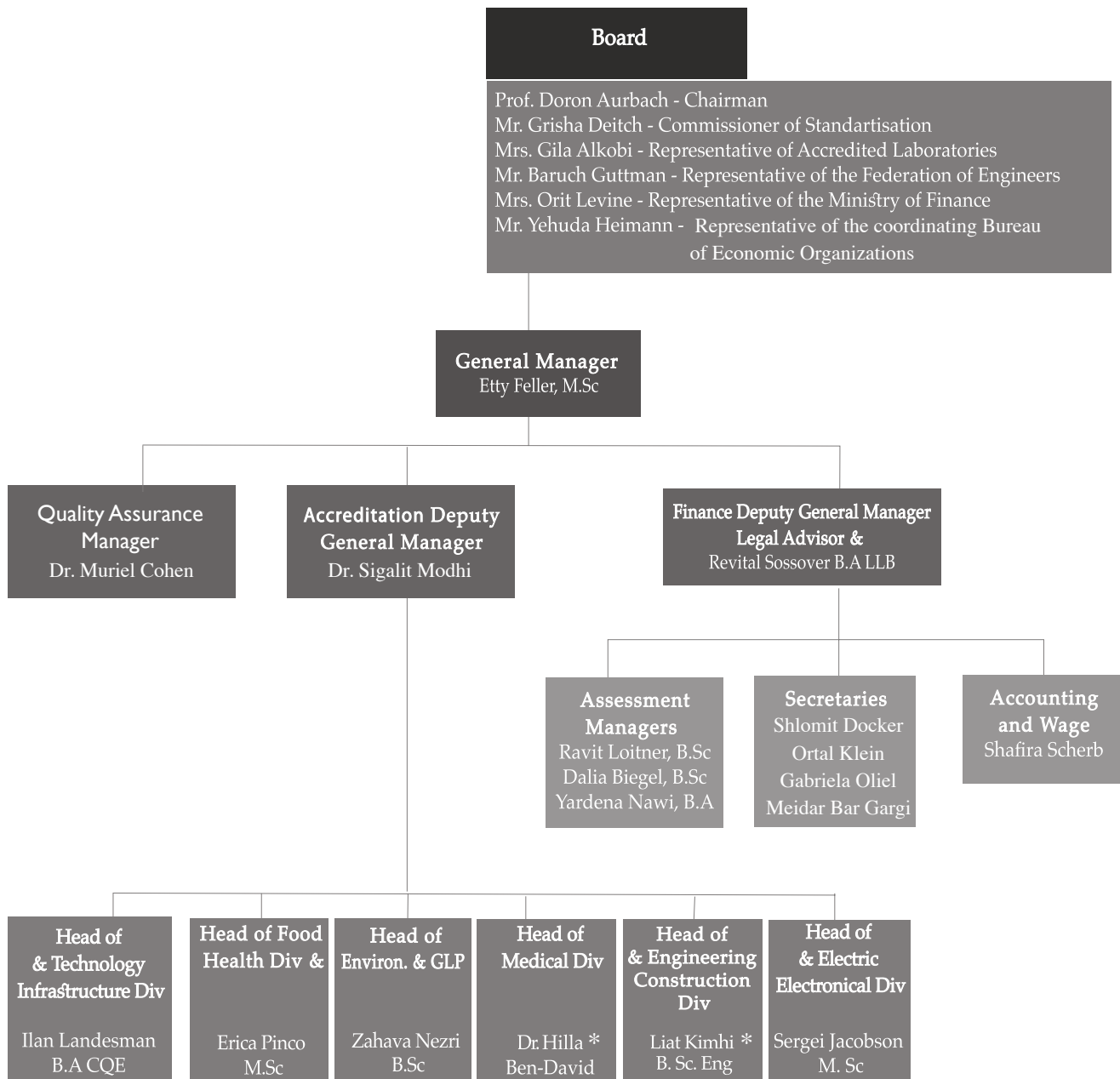
Etty Feller

General Manager





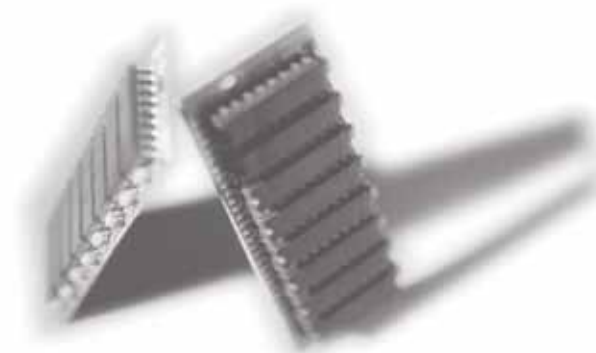
Organization chart

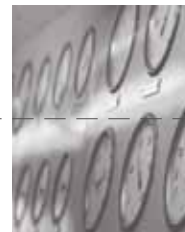


* Dr. Hila Ben David ended her employment at ISRAC in June 2012.

* Liat Kimhi ended her employment at ISRAC in November 2012

* Avi Kivity, Head of the Engineering Division, began his employment at ISRAC in August 2012.





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 said laboratory's professional capabilities and competence to perform specific types calibrations, measurement, sampling and tests. Accreditation is available for all types of activities in any organization, whether part of a factory, or belonging 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 organization to evaluate whether it is performing its work properly and in accordance with international standards.



Important! Accreditation of an organization 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 80 countries that have already signed MRAs for any test or calibration performed by a laboratory accredited by ISRAC. ISRAC is now a full member of the European organization - EA - European Accreditation. The scope of recognition of ISRAC in both organizations includes accreditation for calibration, inspection and testing, including medical laboratories. 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 facilitates 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 in America. In 2004, an assessment was conducted by a team from the OECD. In light of the success of the assessments, Israel was accepted, in 2004, as a full member in the GLP committee of the OECD.

Israeli research facilities conducting preclinical experiments in the fields of pharmaceuticals, cosmetics, pesticides, food additives and environmental toxicity are required to receive recognition that they operate in accordance with the GLP principles.

ISRAC conducts assessments under the directives of the OECD, EPA and FDA.

In 2012 - 15 pre-clinical research facilities are recognized. The facilities are recognized by all the countries of the OECD and can conduct research for companies in Israel and throughout the world that will constitute an acceptable basis for registering medications, toxins, pesticides, food additives and cosmetics in the European market and the OECD.

ISRAC employees take an active part in the activities of the working committee of OECD-GLP. During 2012, a representative of ISRAC participated in an international assessment of the corresponding authorities in Japan.

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

Accreditation is available for every type of sampling, testing, measuring or calibrating which is recorded appropriately. At present, ISRAC gives accreditation in the fields specified below. ISRAC's areas of activity have been updated in the records – The Official Magazine 6397 on 29th March 2012.

They include:

Construction – Chemical, Mechanical, Physical and Engineering Testing

- Concrete
- Concrete products



- Cement
- Materials and construction products
- Steel reinforced concrete
- Building systems (including sprinklers and smoke detectors for fire extinguishers)
- Building casing
- Building carpentry

Soil and Paving – Chemical, Mechanical and Physical Testing

- Base
- Asphalts and bentonite

Food, Water and Beverages – Biological, Chemical and Physical Testing

- Unprocessed and processed food, food additives and supplements, including herbs, spices and carriers.
- Pesticide residues
- Pollutant residues
- Work surface and storage containers testing
- Drinking water testing
- Recreational water testing
- Waste and effluent water testing, including pollution caused by the waste water.

Cosmetics – Biological, Chemical and Physical Testing.

- Chemical testing

Fuels, Oils and Bitumens

- Biological, chemical, physical and engineering testing
- Testing leaks from pipes and mobile, motorised or stationary containers.

Calibration

- Chemical, mechanical, physical and electrical quantities
- Legal metrology for mechanical quantities, physical quantities, chemical quantities, electrical quantities, flow rate meters, liquid meters and scales.

Engineering Items and Non Destructive Testing (NDT)

- Radiography
- Ultrasonic
- Magnetic particles
- Penetrating colours
- Turbulence Flow
- Visibility
- Leak detection

Metallic and Nonmetallic Materials

- Chemical, physical and engineering testing

Environment – Biological, Chemical, Physical and Engineering Testing

- Various types of water

- Waste, effluent, surface water, sea and beach water
- Sludge land, solid waste and flood waters
- Air including ambient air, stationary sources and work environment

- Asphalts and petroleum products

Electricity – Electrical, Physical and Engineering Testing

- Electromagnetic Compatibility (EMC)
- Telephony
- Product safety

Alcoholic Beverages

- According to alcoholic beverage instructions

Health - Biological, Chemical and Physical Testing

- Medicine
- Legal medicine
- Medical research
- Air including ambient air, stationary sources and work environment
- Noise
- Agricultural products

Lifting Devices

Gas Cylinders

Computerized information

Animal Food - Biological, Chemical and Physical Testing

Agriculture – Diagnosis of Plant Pests, Biological, Chemical and Physical Testing

Animal Body Fluids and Tissues - Biological, Chemical and Physical Testing

Medical Products and Medical Devices

- Biological, Chemical and Physical and Engineering Testing

Inter-Laboratory Proficiency Testing (PT)



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* The above information is correct for the year 2012. Updated information can be found on our website: www.israc.gov.il





Main activities during 2012

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 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

7 new laboratories were accredited in 2012.

The total number of accredited organizations at the end of 2012 reached 168, compared to 161 at the end of 2011.

No significant breakthrough in the number of accredited medical laboratories happened in spite of the fact that this area has great potential. However, numerous extension assessments were conducted in accredited laboratories.

Cooperation with international accreditation and standardization organizations

ISRAC has active representatives in the following organizations:

- EA - European Accreditation
- ILAC - International Laboratory Accreditation Cooperation - ISRAC's General Manager was appointed one of the executive committee of the International Laboratory Accreditation Corporation.
- OECD - Organization for Economic Co-operation and Development.

The world financial crisis

ISRAC was not affected by the economic crisis in 2012.

ISRAC maintained its clients and even succeeded in extending its accreditation activities.





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) Plant diseases	- ✓ ✓	✓ ✓ ✓ (partial)
Defense	All fields	✓	No labs
Trade, Labour & Industry	Commissioner of standards (official standards) Radiation Industrial hygiene Noise	✓ - ✓ ✓	No labs No labs ✓ ✓
Environmental Protection	Radiation Soil, wastewater, fuels Air Quality Pesticides	In process Partial ✓ In process	No labs No labs No labs No labs
Internal Affairs	Population of buildings (form 4) Construction	✓ (Except SII) ✓ (Except SII)	No labs No labs
Infrastructure	Fuel Water meters Water Quality	✓ ✓ -	No labs No labs ✓
Transportation	Vehicles Traffic control devices	- -	No labs No labs
Housing and Construction	Construction	✓ (Except SII)	No labs
Homeland Security	Forensic Science Traffic Police	-	✓
	Traffic Police	Beginning the process	No labs



The main activities planned for the year 2013

- 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.



Budget for 2012 and 2013

Budget for 2012 and 2013

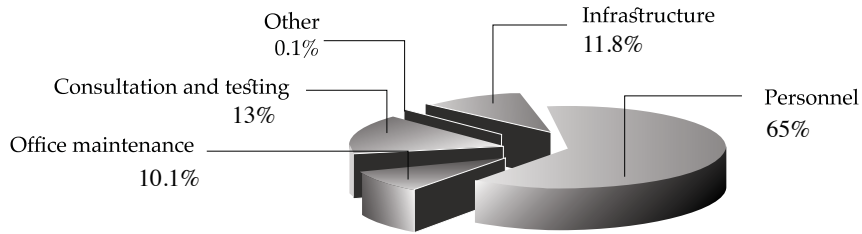
	2012 Budget	2013 Budget	Nominal change
	NIS 000's	NIS 000's	%
Expenditure			
Regular Operations	6,045.1	6,798.4	12.5%
Development	3,178.8	3,174.1	-0.1%
Total Expenditure	9,223.9	9,972.5	8.1%
Income from Operations			
Accreditation and surveillance	5,008.7	5,128.4	2.4%
Training and GLP Inspection	195.0	195.0	0.0%
Total Income from Operations	5,203.7	5,323.4	2.3%
Income from Funding			
Funding of Development - State Budget	3,000.0	3,000.0	0.0%
Regular Funding- State Budget	0.0	0.0	0.0
Peceding Year's Surplus	870.2	1,499.1	72.3%
Income from Interest	150.0	150.0	0.0%
Total Income from Funding	4,020.2	4,649.1	15.6%
Total Income	9,223.9	9,972.5	8.1%
Comment:			

Expenditure

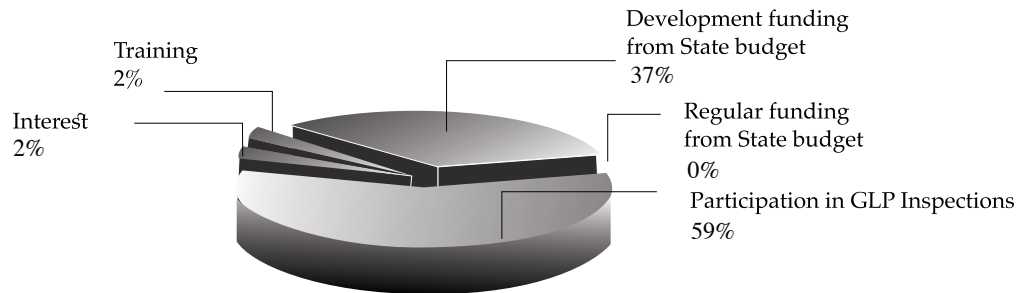
		2012 Budget	2013 Budget	Nominal change
		NIS 000's	NIS 000's	%
Expenditure				
1.0	Personnel	5,997.4	6,060.9	1.1%
2.0	Consultation and Testing	1,196.9	1,984.7	65.8%
3.0	Office Maintenance	930.1	966.3	3.9%
4.0	Other	10.0	10.0	0.0%
	Total Operating Expenditure	8,134.5	9,021.8	10.9%
	Development Element	-2,547.3	-2,628.1	3.2%
	Total Regular Operations	5,587.2	6,393.7	14.4%
5.0	Infrastructure	1,089.4	950.7	-12.7%
	Development Components	2,547.3	2,628.1	3.2%
	Total Development	3,636.6	3,578.8	-1.6%
Total		9,223.9	9,972.5	8.1%



Breakdown of Expenditure in 2011



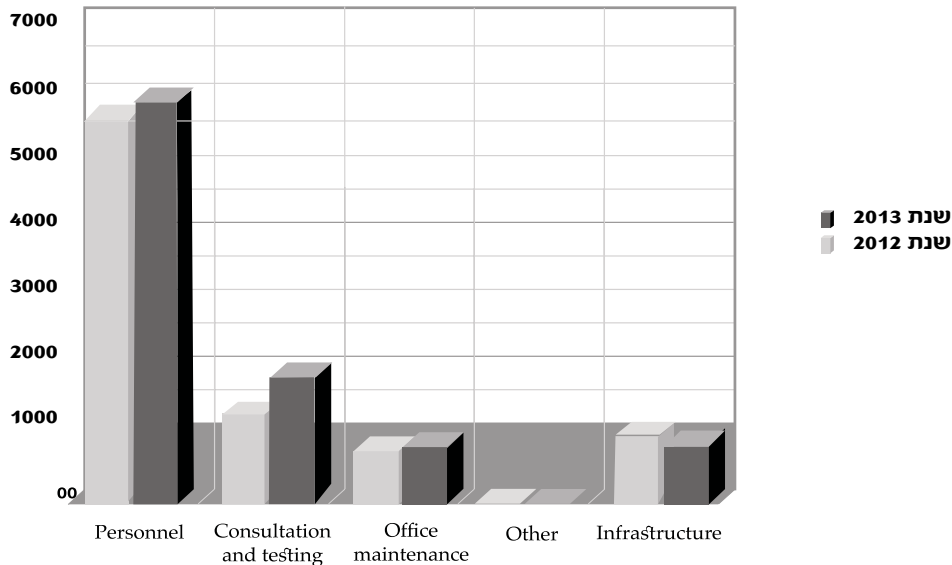
Breakdown of income in 2011



As of January 2013, 153 laboratories have received accreditation, and 15 research facilities received recognition to GLP. 10 laboratories are in the process of accreditation.

Department	No. of accredited labs	No. of labs in the process of accreditation
Engineering	25	2
Health	28	0
Environment	18	0
Medical	20	0
Electric & Electronics	32	4
Infrastructure	30	4
GLP (accreditation)	15	0

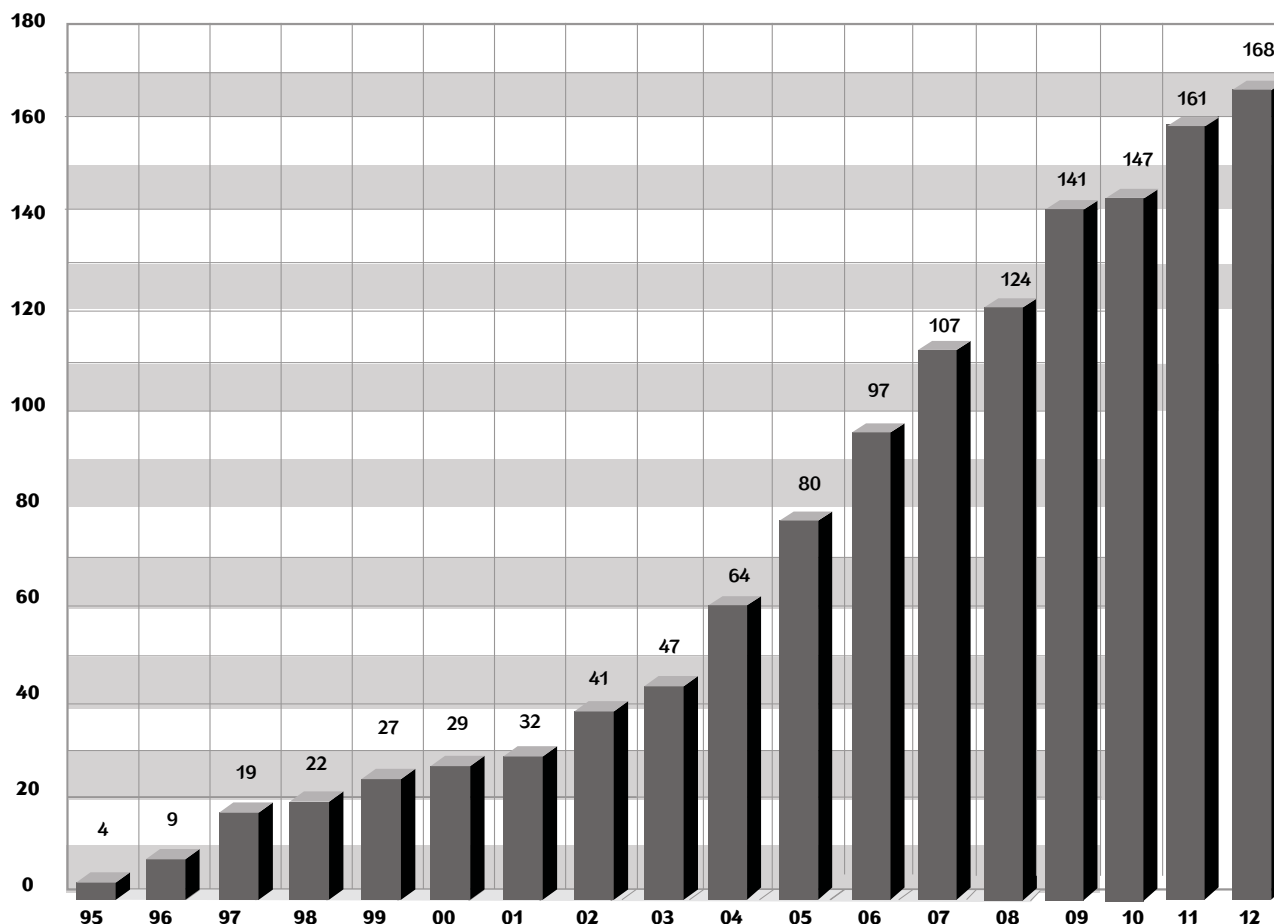
Forecast of Expenditure in the 2013 Budget in Comparison with the 2012 Budget:





The growth in the number of accredited laboratories

According to ISRAC's years of operation (including the preceding advisory committee)



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.