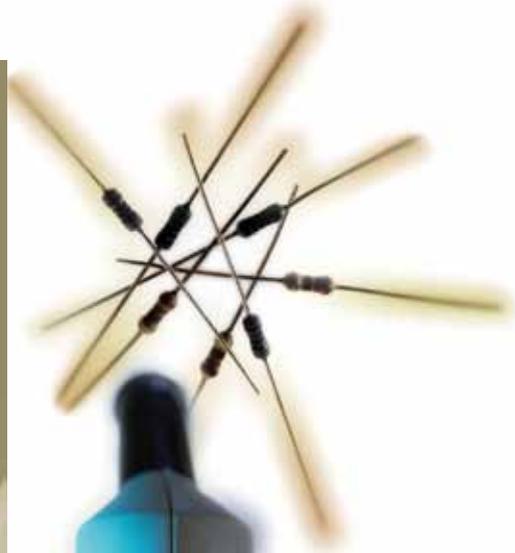
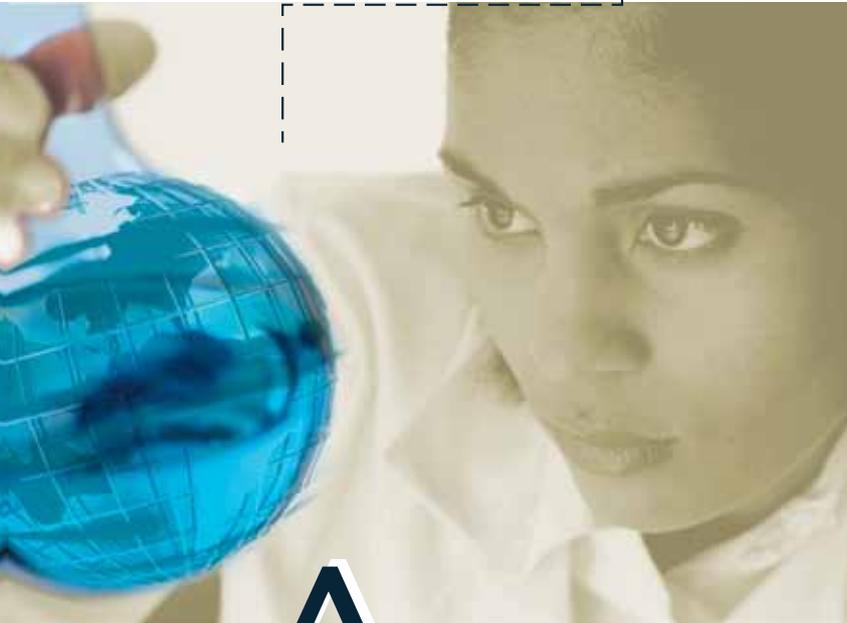




Ministry of Industry, Trade & Labor



**ISRAC**  
Israel Laboratory Accreditation Authority



# Annual Report

Year

2013





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## From the Chairman of ISRAC

The year of 2013 marked many challenges and achievements for all of us, including development of new accreditation areas, improving infrastructure, keeping well our 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 improve further our services, strengthening collaboration with regulators with which we work and more.

ISRAC was established about 17 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 brief, the achievements of ISRAC for 2013 and its status at the beginning of 2014 can be summarized as follows:

The Authority provides current accreditation to 157 laboratories in different testing areas. During 2013, 7 new organizations were added to the list while for 9 other laboratories accreditation had to be cancelled. 13 other new organizations are in the middle of processes to obtain formal accreditation from ISRAC.

The authority is active internationally in all the working committees of ILAC and EA plus an active involvement in the important working committee of GLP-OECD.

The representation and status of ISRAC in all of these international forums is very high and appreciable. ISRAC develops new important accreditation activities related to monitoring fuels, fuels' vapor, tachygraphy calibration and more.

3 new professional committees were elaborated for the following three important goals:

1. Development of new, acceptable criteria for accreditation of medical labs.
2. Development of protocols for examining piping and infrastructure for water and drainage.
3. Development of protocols for examining the status of land/ground/soil for big transportation projects (e.g. erecting new highways, railroads etc.)

A new computerized management program for ISRAC was put in work during 2013. The authority provide tutorials in examination and inspection processes and standards for many customers: laboratories and manpower (e.g. inspectors and examiners who serve ISRAC). ISRAC operates more than 100 outside examiners that help the organization on a daily matter with the current accreditation activities with all the labs and organization under the umbrella of ISRAC.

2013 can be considered as a very successful and prolific year for ISRAC.

The authority is now very well connected to the most important accreditation organizations throughout the world. The international recognition in the inspection activity of ISRAC was impressively broadened during 2013. Just to

remind: 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. Since then, the relationship with this important European organization was strengthened pronouncedly. 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, according to the principles of OCED-GLP. The relationship of ISRAC and ILAC were remarkably strengthened during 2013. 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 ISRAC has with all the formal Israeli governmental bodies with whom it works, including the Ministries of Finance, Agriculture, Industry and Commerce, Environment and Law.

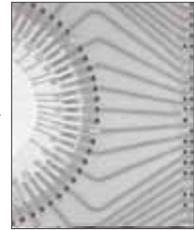
Over the years ISRAC has demonstrated a very balanced and responsible operation from the financial point of view. The annual reports always reflected a balanced and reasonable budget. Consequently, we benefit from the cooperation and full confidence of all the governmental bodies with whom we work. In terms of legislation activity: we are waiting to the expected updating and upgrading 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 2013. In fact, ISRAC started with an 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 processes started during 2012 continued very well during 2013 and are expected to be completed during 2014. I mention again with a great satisfaction the successful and highly prolific teaching activity of ISRAC, during 2013.

Since ISRAC is a dynamic organization, there were some changes in its personnel: Mr. Adi Tamari joined the organization as the head of the food and health branch. This letter is written after we celebrated 66 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 the state of Israel 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 everything of the best, good health and happiness.

Sincerely yours,  
**Prof. Doron Aurbach**



## From the General Manager

In 2013 ISRAC staff completed its transformation to a new monitoring method, a re-accreditation once in two years, subject to our board decision

The year 2013 summoned many challenges for us all. Challenges which combined: developing areas of accreditation, maintaining accredited organizations in light of the economic turmoil and improving infrastructure.

ISRAC has 157 accredited organizations and a new 13 organizations in process towards receiving accreditation. During the year accredited organizations expanded their accreditation scope with a dozen new technologies. New accreditation areas were accredited as a result of our active effort with regulators and stakeholders.

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 recognition requirements. New areas of accreditation in 2013: Fuel vapor recovery, Techograph calibration and Fitness equipment.

During the year the general manager Advisory committee was gathering to learn about new areas in which we can develop in to. A Technical committee was gathering also to recommend changes according to a new medical laboratory accreditation standard ISO 15189 (2012). Its recommendations were successfully implemented in ISRAC guiding procedures.

At the ILAC General Assembly in October 2013, the representatives of the member organizations agreed to confirm ISRAC general manager nomination as the chairman of the Arrangement Management Committee

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

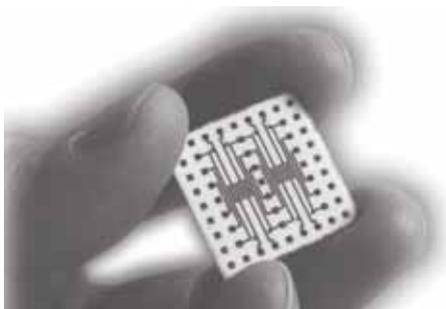
The Law of the Authority is still in the process of being updated and we hope that the coming year will bring "news". The updating of the Law is very significant to the widening of ISRAC's activities to fields which up until now, ISRAC has precluded from engaging in. On one hand, regulators seek to accredit areas of inspection and to certify management systems, and on 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 and assessors. This program has been very successful. High degree compliance was registered showing a great interest in our professional training issues.

I wish to thank all ISRAC employees for their effort and willingness to work tirelessly promoting our mission of "...promoting quality and professional competence of calibration / testing bodies working in harmony with the world for the state of Israel and its citizens". To the various regulators who use accreditation as a part of their trusted implementation processes, to the stakeholders and to our public clients who put their trust in ISRAC performance / activities.

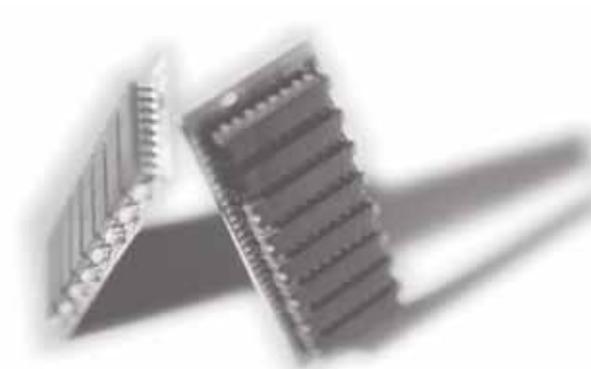
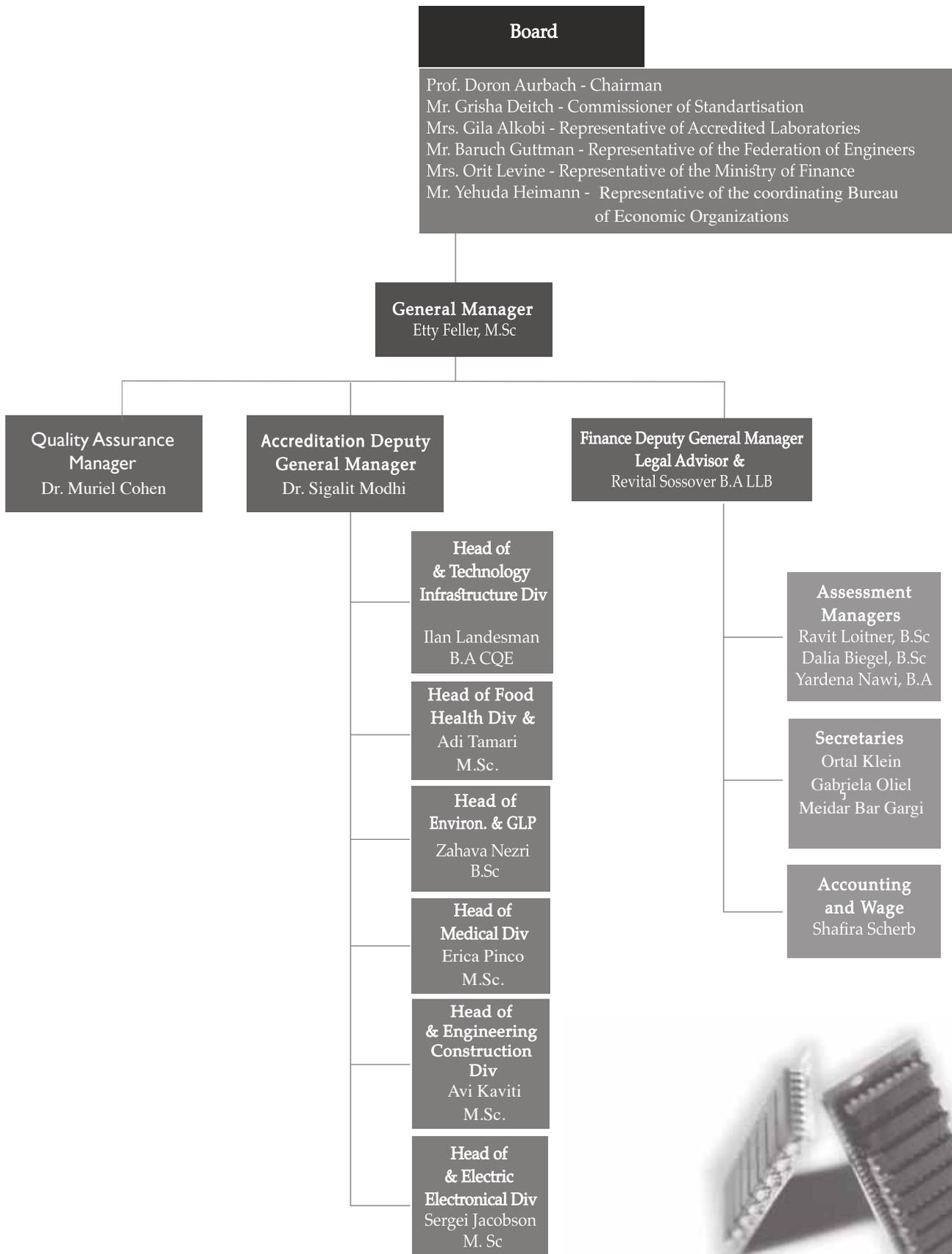
**Etty Feller**

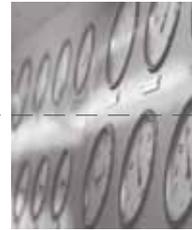
General Manager





## 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 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 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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## Main activities during 2013

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 achieve the same with goals that involved 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 CAB's Conformity Assessment Bodies were accredited in 2012.

The total number of accredited CAB's at the end of 2013 reached 173, compared to 168 at the end of 2012. 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 2013.

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





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



## The main activities planned for the year 2014

- Approval of the ISRAC law.
- Increasing the number of accredited organizations and increasing the scope of accreditation of the existing accredited organizations.
- Organizing professional training improve quality and professionalism in accredited organizations
- Developing new areas of accreditation.
- Upgrading ISRAC's website.
- 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 2013 and 2014

	2013 Budget	2014 Budget	Nominal change
	NIS 000's	NIS 000's	%
<b>Expenditure</b>			
Regular Operations	6,798.4	6,904.8	1.6%
Development	3,174.1	3,201.6	0.9%
<b>Total Expenditure</b>	<b>9,972.5</b>	<b>10,106.4</b>	<b>1.3%</b>
<b>Income from Operations</b>			
Accreditation and surveillance	5,128.4	5,200.2	1.4%
Training and GLP Inspection	195.0	96.0	-50.8%
<b>Total Income from Operations</b>	<b>5,323.4</b>	<b>5,296.2</b>	<b>-0.5%</b>
<b>Income from Funding</b>			
Funding of Development - State Budget	3,000.0	3,000.0	0.9%
Regular Funding- State Budget	0.0	0	0
Peceding Year's Surplus	1,499.1	1,660.2	10.7%
Income from Interest	150.0	150.0	0.0%
<b>Total Income from Funding</b>	<b>4,649.1</b>	<b>4,810.2</b>	<b>3.5%</b>
<b>Total Income</b>	<b>9,972.5</b>	<b>10,106.4</b>	<b>1.3%</b>

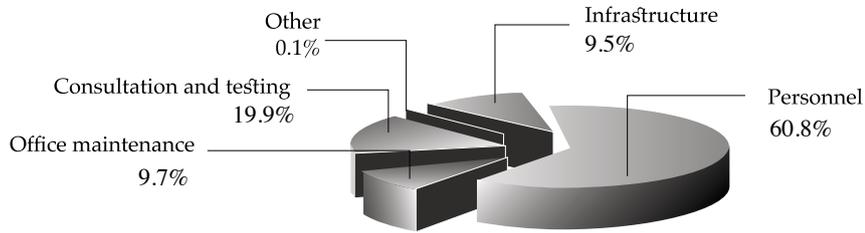
Remark: Development percentage is updated (relevant to previous years) according to the Economy office's instructions.

### Expenditure

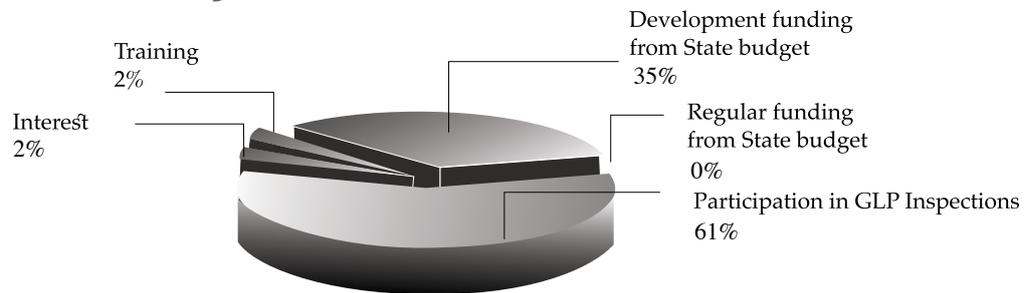
		2013 Budget	2014 Budget	Nominal change
		NIS 000's	NIS 000's	%
<b>Expenditure</b>				
1.0	Personnel	6,060.9	6,017.0	-0.7%
2.0	Consultation and Testing	1,984.7	2,054.0	3.5%
3.0	Office Maintenance	966.3	981.6	1.6%
4.0	Other	10.0	10.0	0.0%
	<b>Total Operating Expenditure</b>	<b>9,021.8</b>	<b>9,062.5</b>	<b>0.5%</b>
	Development Element	-2,628.1	-2,606.5	-0.8%
	<b>Total Regular Operations</b>	<b>6,393.7</b>	<b>6,456.0</b>	<b>1.0%</b>
5.0	Infrastructure	950.7	1,043.9	9.8%
	Development Components	2,628.1	2,606.5	-0.8%
	<b>Total Development</b>	<b>3,578.8</b>	<b>3,650.3</b>	<b>2.0%</b>
<b>Total</b>		<b>9,972.5</b>	<b>10,106.4</b>	<b>1.3%</b>



Breakdown of Expenditure in 2013



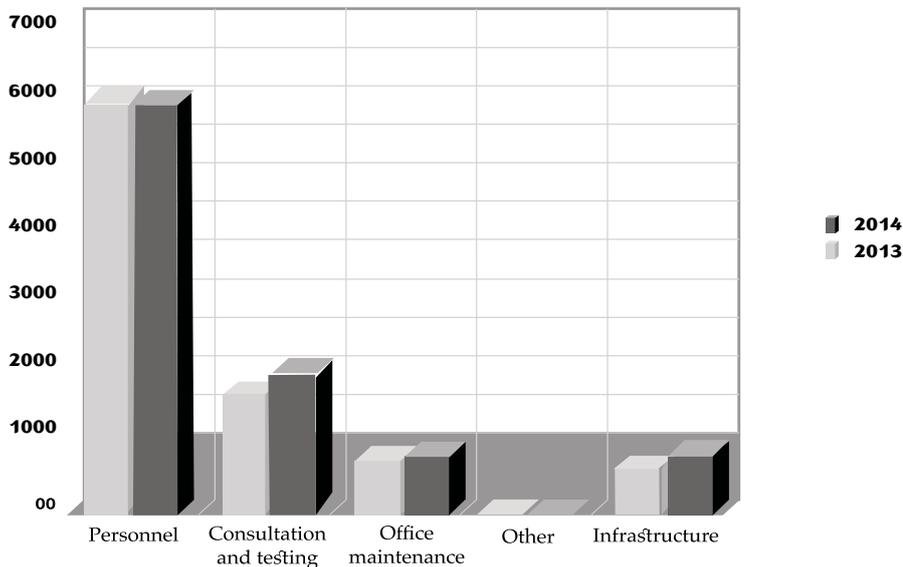
Breakdown of income in 2013



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

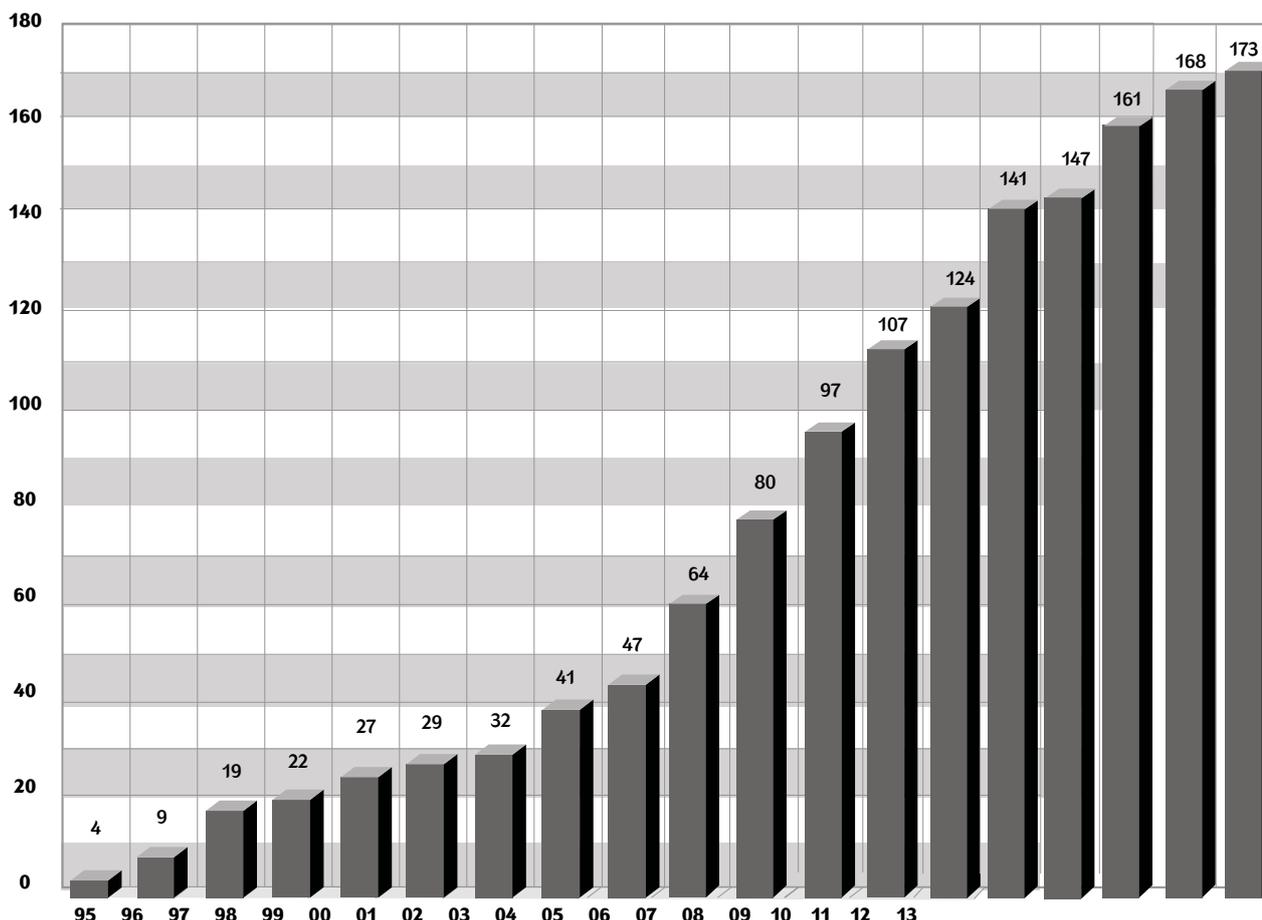
Forecast of Expenditure in the 2014 Budget in Comparison with the 2013 Budget:





## 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](http://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.