



הרשות הלאומית להסמכת מעבדות
Israel Laboratory Accreditation Authority



ANNUAL REPORT

2015

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From the Chairman of ISRAC

The year of 2015 included the renewal of the international recognition 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 to improve further our services, strengthening collaboration with regulators with which we work and more.

ISRAC was established about 19 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 2015 and its status at the beginning of 2016 can be summarized as follows:

The Authority provides current accreditation/ recognition to 189 laboratories.

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 in 2015 vehicle testing new regulations on the request of the Ministry of Transport.

The authority provides 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. 2015 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. 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 organizations. 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 2015. 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.

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

Prof. Doron Aurbach



From the General Manager

2015 has been a diverse year- As every year working with regulators has been very productive and led to professional guiding documents for accreditation.

Another organizational efficiency process has been "a two years' certificate" in effort to improve our correspondence with accredit organizations which need certificates for the duration of the whole accredit period. Our change allows these organizations to apply for tenders and engage with international client as an ongoing process which will final be implemented on 2016.

ISRAC has 189 accredit/recognized organizations during the year accredit organizations expanded their accreditation scope with a dozen new technologies. New accreditation areas were added as a result of our active effort with regulators and stakeholders.

As mentioned above, ISRAC's staff has extended its collaboration with various regulators. This collaboration provides regulators with a tool to monitor developments in their fields without being a burden upon their ongoing activities, their annual budget and especially to those regulators using accreditation services as a part of recognition requirements.

New areas of accreditation in 2015: new regulations testing for cars according to transportation ministry request. During the year the General Manager Consulting Committee was gathered to facilitate new areas of expertise in the purpose of developing new areas of activities.

On October 2015, I am pleased to inform that ILAC General Assembly has approved my Nomination as a chairwoman of Arrangement Management Committee, that has an imperative role in organization's recognition, and screening of signed organizations on mutual recognized agreements., I have presented the international status of the organization, the new countries entrance and the new

accreditation zones that are forming in Africa and Arab states.

Israel Laboratory Accreditation Authority is appointed by the State of Israel, as a monitoring unit according to OECD-GLP principles. Since 2004, ISRAC is a full member of the OECD-GLP working group.

ISARC Law's update is still in an ongoing process an updated law plays a significant role in widening 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 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 economic ramification of updated law and its impact on Israel regulation processes was examined, it was found to have a substantial economic impact in our market. The law memorandum has been completed and we are in the final stages prior submitting it to the economic committee in the legislative branch

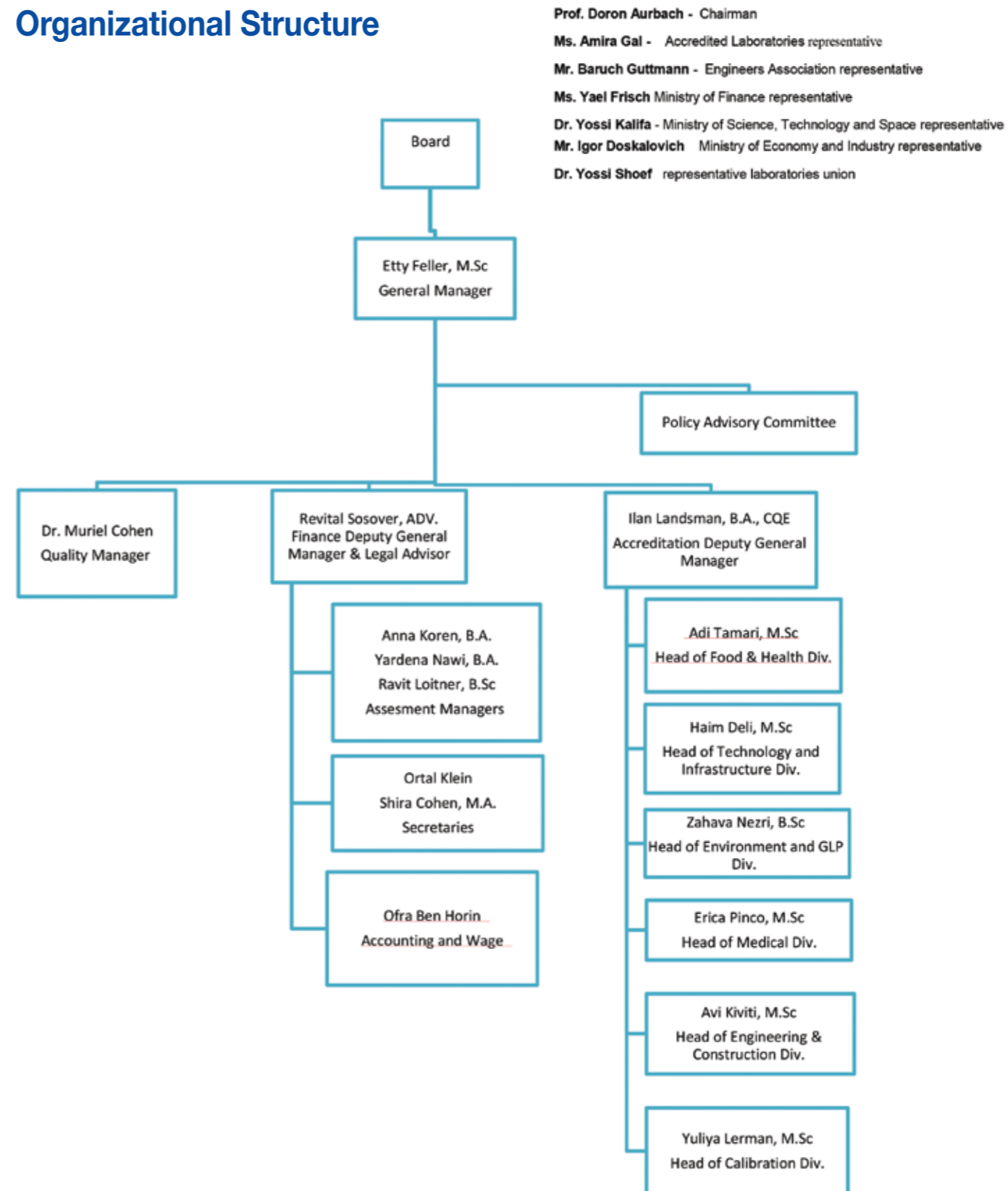
During the year, ISRAC's employees devoted their efforts to build a diverse training program for employees of accredited bodies and assessors. This program has been very successful. High degree compliance was registered showing a great interest in our professional training issues.

We are working for the last 19 years "...promoting quality and professional competence of calibration / testing bodies working in harmony with the world for the state of Israel and its citizens". I wish to thank the regulators whom use accreditation as a part of their trusted implementation processes, to the stakeholders and to our public clients who put their trust in ISRAC's performance and activities

Etty Feller



Organizational Structure



- Prof. Doron Aurbach - Chairman
- Ms. Amira Gal - Accredited Laboratories representative
- Mr. Baruch Guttman - Engineers Association representative
- Ms. Yael Frisch Ministry of Finance representative
- Dr. Yossi Kalifa - Ministry of Science, Technology and Space representative
- Mr. Igor Doskalovich Ministry of Economy and Industry representative
- Dr. Yossi Shoef representative laboratories union

Mr. Shimon Gordin Samion was our Technology and Infrastructure Head of Division between July 2014 until July 2015. He passed away before his time. God bless his soul.
 Mr. Sergei Yacobson retired as our Head of Electricity and Electric Division on June 2015
 Mr. Haim Deli joined our team on June 2015 as our Electricity and Electric Division on June 2015 and on December 2015 as the Head of Technology and Infrastructure Division.
 Mrs. Yuliya Lerman joined our team on October 2015

About ISRAC

The early 1990's 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 (today called Ministry of Economy and Industry) 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, 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 a laboratory accreditation?

The accreditation of a laboratory implies official recognition of laboratory's professional capabilities and competence to perform specific types of calibrations, measurement, sampling and tests. Accreditation is available for all types of activities in any organization, whether it is a part of a factory, the public or in the 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.

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 recognized 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 86 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, testing and 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 2015- 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's Commitments

The entire staff of ISRAC, including its managers, assessors and consultants sign a confidentiality agreement to protect the confidentiality of information of 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 process appropriately recorded. At present, ISRAC accredits in the following fields:

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 Bitumen

- Biological, chemical, physical and engineering testing
- Testing leaks from pipes and mobile, motorized 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 colors
- 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)

ISRAC contacts' information

Mailing Address: 12 Kinneret St. Airport City, P.O. Box 89 Lod Airport 7015002

Phone: 03-9702727, Fax: 03-9702413

Email: israc@israc.gov.il, Website: www.israc.gov.il

Position	Name	Title	Phone Extension	Email
General Manager	Etty Feller	M.Sc.	03-9702727/208	ettyf@israc.gov.il
Finance Deputy General Manager & Legal Adviser	Revital Sossover	Advocate	03-9702727/206	revitals@israc.gov.il
Accreditation Deputy General Manager	Ilan Landesman	BA, CQE	03-9702727/219	ilanl@israc.gov.il
Quality Manager	Muriel Cohen	Ph.D., MBA	03-9702727/212	Murielc@israc.gov.il
Head of Medical Div.	Erica Pinco	M.Sc.	03-9702727/204	erica@israc.gov.il
Head of Environmental & GLP Div.	Zahava Nezri	B.Sc.	03-9702727/203	zahavan@israc.gov.il
Head of Engineering & Construction Div.	Avi Kivity	M.Sc.	03-9702727/209	avik@israc.gov.il
Head of Food & Health Div.	Adi Tamari	M.Sc.	03-9702727/222	adit@israc.gov.il
Head of Technology and Infrastructure Div.	Haim Deli	M.Sc.	03-9702727/205	haimd@israc.gov.il
Head of Calibration Div.	Yuliya Lerman	M.Sc.	03-9702727/237	yuliyal@israc.gov.il
Assessment Manager	Ravit Loitner	B.Sc.	03-9702727/228	ravitl@israc.gov.il
Assessment Manager	Anna Koren	B.A	03-9702727/201	annak@israc.gov.il
Assessment Manager	Yardena nawi	BA	03-9702727/226	yardena@israc.gov.il
General Manager Secretary and Courses Coordinator	Shira Cohen	M.A	03-9702727/207	shirac@israc.gov.il
Secretary	Ortal Shiro		03-9702727/213	ortals@israc.gov.il
Wage and Accountant Manager	Ofra Ben Horin		03-9702727/209	ofrab@israc.gov.il

Main activities during 2015

Seeking approval to revise ISRAC's law

is an ongoing mission.

The legal department in the Ministry of Economy had issued a detailed document pointing out the need of the state in more tools and means to enhance the enforcement.

The revision of ISRAC's law will facilitate, among other things, the implementation of the new regulations fields and enhancement of enforcement economy.

Accreditation of new laboratories

10 new laboratories were accredited in 2015.

The total number of accredited organizations is 189.

No significant breakthrough in the number of accredited medical laboratories happened in spite of the fact that this area has a 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 unanimously as one of the executive committee of the International Laboratory Accreditation Corporation.
- OECD (Organization for Economic Co-operation and Development) in the field of GLP, (Good Laboratory Practice)

Main activities planned for the year 2016

- Approval of ISRAC law.
- Increasing the number of accredited organizations and increasing the scope of accredited laboratories.
- Organizing professional training and improve quality procedures and professionalism in accredited organizations
- Developing new areas of accreditation.
- Broadening the cooperation between ISRAC and regulators in all government ministries, manufacturers associations, consumer organizations, the Israel Export Institute, the Standards Institution of Israel and the Chamber of Commerce.
- Cooperation with international accreditation and standardization organizations

Regulators cooperation

Government office	Activity fieldw	Requires accreditation	Accredited office labs
Health	Water and food	Yes	None
	Clinical labs	No	Partial
Agriculture	Pesticides	No	Yes
	Pesticides residue	Yes	Yes
	Plant diseases	Yes	Partial
	veterinarian Services	Yes	Partial
Defense	In all areas	Yes	No
Economic	In charge of standards	Yes	No
	Radiation	No	No
	Hygiene	Yes	Yes
	Noise	Yes	No
	Diamond inspector	In process	No
Environment	Radiation	In process	No
	Soil, Sewage, Fuel	In partial	No
	Air Quality	Yes	No
	Pesticides	In process	No
Interior	Occupation of buildings (form number 4)	Yes, except economic ministry	No
	Building	Yes, except economic ministry	No
Infrastructure	Fuel	Yes	No
	Water meters	Yes	No
	Water quality	No	Yes
	Sewage and water infrastructure	In process	No
Transportation	Cars	No	No
	Mobile devices	In process	No
Building and occupation	Building	Yes except economic ministry	No
Interior defense	Forensic	No	Yes
	Transportation police	Yes	No

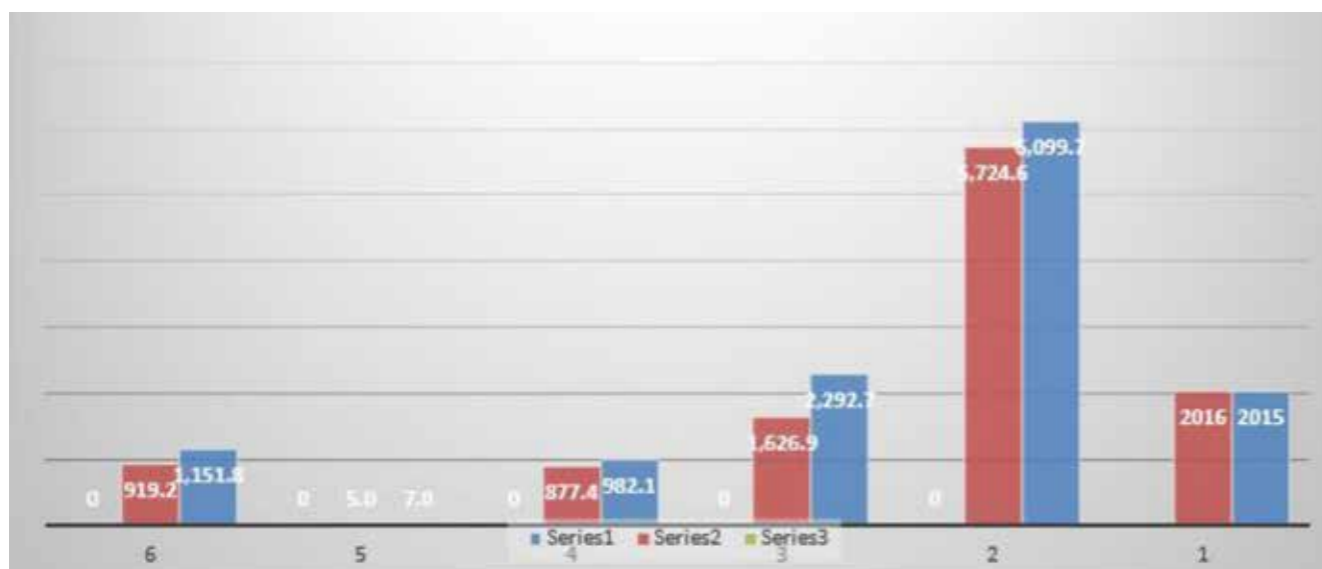
Budget for 2015 and 2016

	2015 Budget NIS 000's	2016 Budget NIS 000's	Nominal Change %
Expenditure			
Regular Operations	7,251.2	6,047.9	-16.60%
Development	3,282.1	3,105.1	-5.40%
Total Expenditure	10,533.3	9,153.0	-13.10%
Income from Operations			
Accreditation and surveillance	5,825.8	5,288.8	-9.20%
Training	72.0	78.0	8.30%
Total Income from Operations	5,897.8	5,366.8	-9.00%
Income from Funding			
Funding of development	3,000.0	2,800.0	-5.40%
from state budget			
Regular funding from state budget			
Financed balance deficit	1,485.5	936.2	-57.20%
Interest income	150.0	50.0	0.00%
Total income financed	4,635.5	3,786.2	-18.30%
Total Income	10,533.3	9,153.0	-13.10%

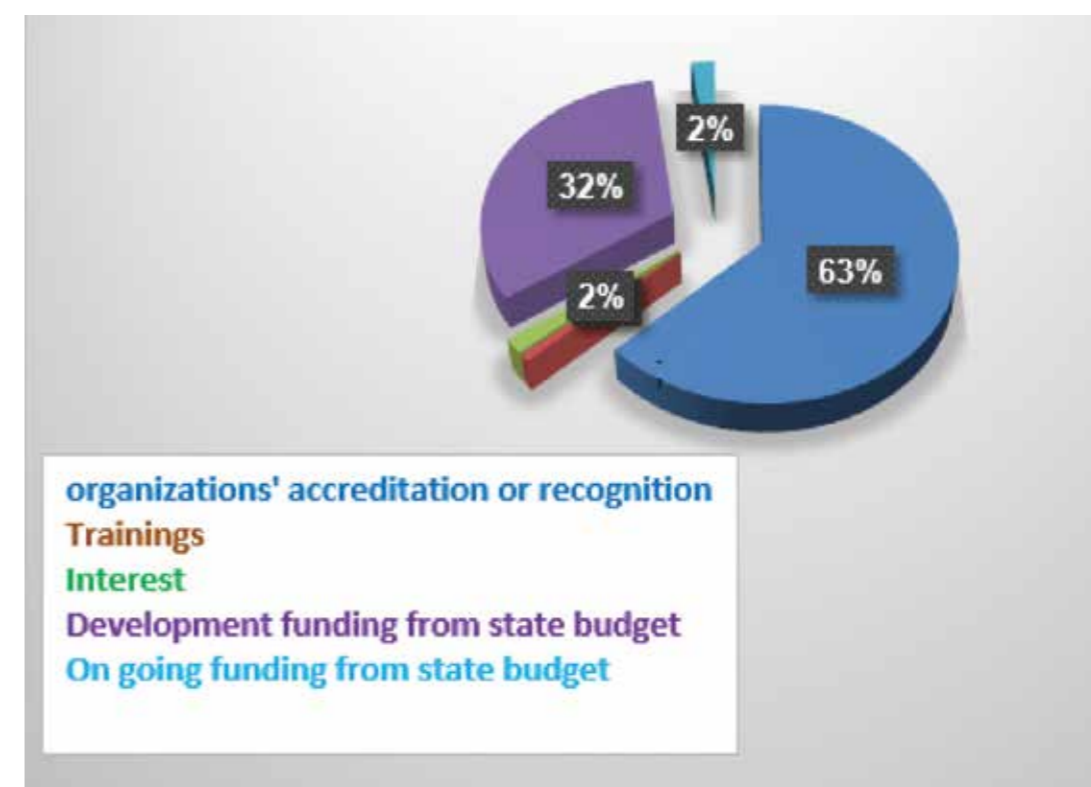
Remark: Insurance rates have been updated (in previous years) in accordance with the instructions of the Ministry of Economy and Industry

	2015 Budget NIS 000's	2016 Budget NIS 000's	Nominal change
Expenditure			
1 Personnel	6,099.7	5,724.6	-6.2%
2 Consultation and testing	2,292.7	1,626.9	-29.0%
3 Office maintenance	982.1	877.4	-10.7%
4 Other	7.0	5.0	-28.6%
Total Operating Expenditure	9,381.5	8,233.8	-12.2%
Development Element	-2,618.9	-2,562.1	-2.2%
Total Regular Operations	6,762.6	5,671.7	-16.1%
5 Infrastructure	619.9	543.0	-12.4%
Development Components	2,618.9	2,562.1	-2.2%
Total Development	3,238.8	3,105.1	-4.1%

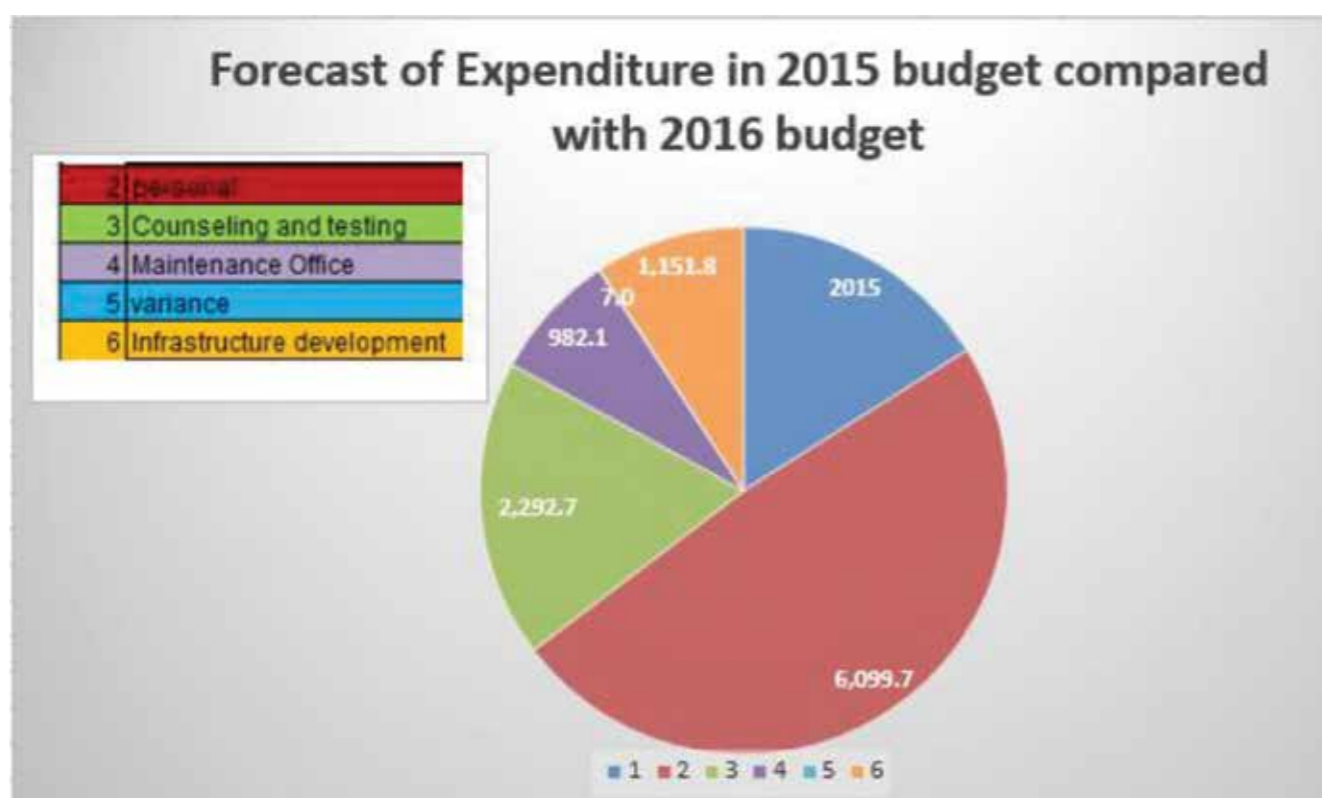
Forecast of Expenditure in 2015 budget compared with 2016 budget



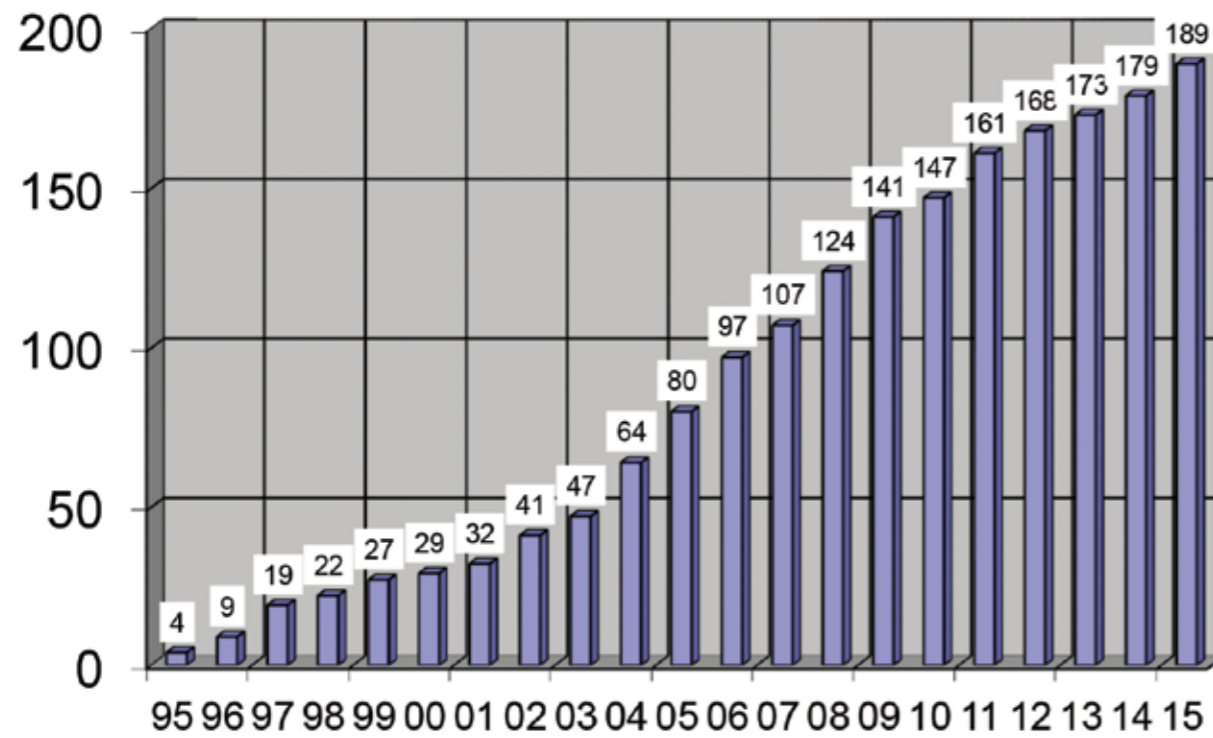
Income		2015 NIS 000's	2016 NIS 000's
1	organizations' accreditation or recognition	5,825.8	5,288.8
2	Training	72.0	78.0
3	Interest	150.0	50.0
	Development funding from state budget	3,000.0	2,800.0
	ongoing funding from state budget	200.0	200.0



Forecast of Expenditure in 2015 budget compared with 2016 budget



The growth in number of accredited laboratories



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 be a transparent organization and as such publishes its activities for the public not excluding our clients, regulators and interested bodies.

Our quarterly newsletter and quality manual (for accreditation and GLP) are published on our website www.israc.gov.il that also provides a list of ISRAC accredited laboratories including their scope of accreditation, as well as ISRAC guidelines and extensive additional information bilingually (Hebrew and English).

The "Reshuton" is distributed to 2,500 readers. 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 about 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 07:30 AM – 4:30 PM by appointment.