



הרשות הלאומית להסמכת מעבדות
Israel Laboratory Accreditation Authority



ANNUAL REPORT

2016

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From the Chairman of Israel Laboratory Accreditation Authority

2016 included a renewal of international recognition by the OECD, developing new areas of accreditation, assessment accredited organizations and improvement of infrastructure in the shadow of the economic upheavals.

ISRAC team based its cooperation with various regulators. This collaboration gives regulators a tool supervising in their fields, without being a burden on their current activities and their annual budget especially those who use the services of accreditation as a part of the requirements for approval or recognition.

ISRAC was established about 19 years ago as a national body of great importance. Scattered across the country are hundreds of laboratories that provide analytical services in the fields of medicine, engineering, chemistry, construction, and agriculture. Israeli citizens' health, security and the economy dependent on the reliability of these analytical services. The public and Israel industry putting their trust on the quality of products for import and export purposes. Without a question, in our country, the Israel Laboratory Accreditation Authority is the only official tool to conserve high standards in all laboratories that provide testing and calibration services. These standards generally accepted and applied in most advanced countries.

The situation at the end of 2016:

196 organizations accredited / recognized.

ISRAC is an active member in international level at all working committees of ILAC, EA and OECD-GLP. There is a high and a very dignified class representation of ISRAC members in international forums.

ISRAC currently employs 100 assessors, whom monitor laboratories under accreditation umbrella to ensure that the accreditation granted by ISRAC is on a professional firm base. 2016 is considered a successful and fruitful year for ISRAC, no less than its previous ones.

ISRAC is well connected to international accreditation organizations. Israel Laboratory Accreditation Authority has myopathy power of the state of Israel to supervise according to the OECD principles of GLP. ISRAC is a full member of OECD-GLP committee since 2004.

As for legislation relating to ISRAC:

ISRAC Act has still being updated. Revision of the law has very significant implications of ISRAC areas of accreditation, which so far ISRAC is prevented from approaching them. On one hand, regulators request to accredit supervision areas and document management system. On the other hand, assessors and supervisors that are needed for this activity are requested to receive it from other foreign sources. Furthermore, advanced

acts such as Natural Gas Act allow ISRAC to accredit inspection bodies in this area.

ISRAC conducts training courses for her clients and assessors to help in understanding and implementing the accreditation requirements. These courses were in high demands expressing great interest on professional training issues.

ISRAC site provides updated procedures and all accredited laboratories list and its accreditation scope of technologies.

I must note with great satisfaction the good relations between ISRAC and various government offices with whom we work, including the Ministry of Finance, Ministry of Agriculture, Ministry of Economy and Industry, Ministry of Environment and the Ministry of Justice.

Over the years, ISRAC funds have been managing in a balanced, responsible manner, transparent in published ISRAC annual reports. As a result, ISRAC enjoys the cooperation and trust of governmental bodies, which it works with.

Israel Laboratory Accreditation Authority maintains high standards of work, reliability and integrity. I wish for the continuation of a great and fruitful contribution to the state of Israel.

In August of this year, I resign from six years term as the chairperson of ISRAC. Following ISRAC law, after two terms of 3 years each, I must resign. Prof. Israel Schechter from the Faculty of Chemistry in Technion will occupy my position. I rejoice the decision. Prof. Schechter is the country's leading scientists on Chemical Analytical, has a vast experience in laboratories management, development of innovative measurement techniques and extensive activities demonstration on national and international front.

I am glad for the opportunity to be a part of ISRAC. ISRAC is blessed with an excellent work force, hardworking, responsible and visionary personal, who do their job loyalty with a sense of a mission. Indeed, ISRAC contributes dearly to Israel status as a part of developed and civilized countries. I had the privilege to work with a developed body, which keep developing, and I leave you feeling satisfied and full confidence in the ability of ISRAC to continue developing and leading the way for a standardized country.

Finally, I would like to thank my ISRAC colleagues at all levels on their dedication in maintaining a high standard of work. I also thank ISRAC Council members on the concern and responsibility they have shown in their voluntary role at the council.

I wish you all the best, good health and happiness.

Prof. Doron Aurbach

From the General Manager

2016 has been a diverse year- As every year working with regulators has been very productive and led to professional guiding documents for accreditation and implementation of accreditation in new acts.

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 cliental

ISRAC has 196 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 11 organization were accredited and four withdrawn its accreditation.

As mentioned above, ISRAC 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 2016: new regulations testing for cars according to transportation ministry request.

During the year, the General Manager Consulting Committee was gathered twice to facilitate new areas of expertise in the purpose of developing new areas of activities.

On November 2016, I am pleased to inform that ILAC General Assembly has approved my Nomination as the vice chairperson of ILAC. It 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, new countries entrance and the accreditation zones that are forming in Africa and Arab states.

Israel Laboratory Accreditation Authority has myopathy power of the state of Israel to supervise according to the OECD principles of GLP. Since 2004, ISRAC is a full member of the OECD-GLP working group. The MJV was during January 2016 No deviations were observe.

ISARC Law's update is still in an ongoing process.

During the year, ISRAC team devoted their efforts to build a diverse training program for accredited bodies personal and assessors. It is a very successful one with a high degree of compliance showing a great interest in our professional training issues.

We are working for the last 20 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 thank various regulators whom use accreditation as a part of their enforcement process on which they are liable of and to stakeholders and our clients on their trust of ISRAC activities.

I look forward to ISRAC's continuing excellent and prolific contribution to our society.

Etty Feller

Organizational Structure

The Board up until Oct 2016

Prof. Doron Aurbach - Chairman

Mr. Baruch Guttmann - Engineers Association Representative

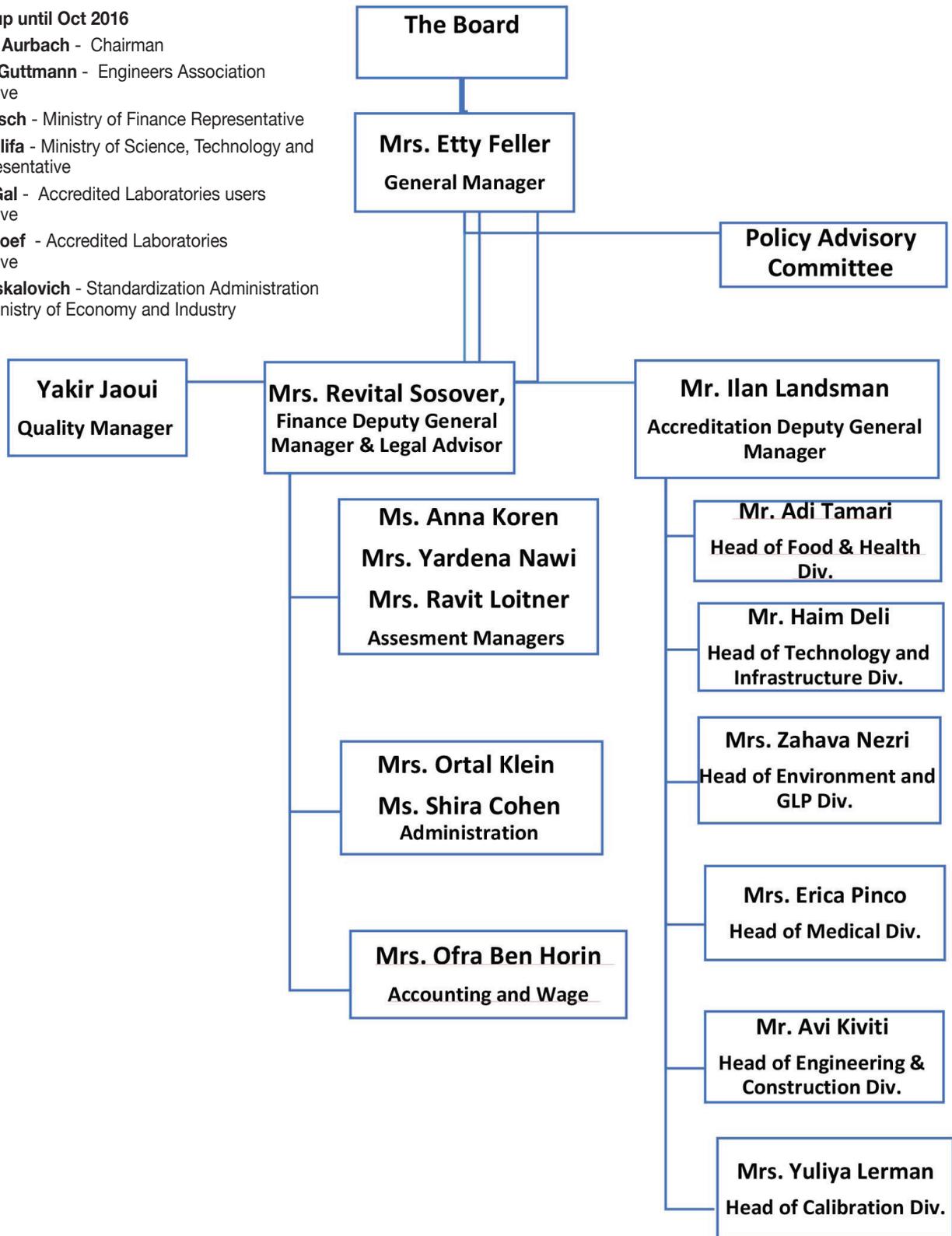
Ms. Yael Frisch - Ministry of Finance Representative

Dr. Yossi Kalifa - Ministry of Science, Technology and Space Representative

Ms. Amira Gal - Accredited Laboratories users Representative

Dr. Yossi Shoef - Accredited Laboratories Representative

Mr. Igor Doskalovich - Standardization Administration Nominee, Ministry of Economy and Industry



About ISRAC

The early nineties 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 in addition, information.

What is a laboratory accreditation?

The accreditation of a laboratory implies official recognition of laboratory's professional capabilities and competence to perform specific type's 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.

Important Information!

Accreditation provides formal recognition to organization ability and employee professional competence and therefore indicates a mean to large consumer and clients like enforcement authorities a guarantee of liable and quality service for testing, measurement 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 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, a team from the OECD conducted an assessment. 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 Ethics and Confidentiality

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:

1. Construction - Chemical, Mechanical, Physical and Engineering Testing

- 1.1 Concrete
- 1.2 Concrete products
- 1.3 Cement
- 1.4 Materials and construction products
- 1.5 Steel reinforced concrete
- 1.6 Building systems (including sprinklers and smoke detectors for fire extinguishers)
- 1.7 Building casing
- 1.8 Building carpentry

2. Soil and Paving - Chemical, Mechanical and Physical Testing

- 2.1 Base
- 2.2 Asphalts and bentonite

3. Food, Water and Beverages - Biological, Chemical and Physical Testing

- 3.1 Unprocessed and processed food, food additives and supplements, including herbs, spices and carriers.
- 3.2 Pesticide residues
- 3.3 Pollutant residues
- 3.4 Work surface and storage containers testing
- 3.5 Drinking water testing
- 3.6 Recreational water testing
- 3.7 Waste and effluent water testing, including pollution caused by the wastewater.

4. Cosmetics - Biological, Chemical and Physical Testing.

- 4.1 Chemical testing

5. Fuels, Oils and Bitumen

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

6. Calibration

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

7. Engineering Items and Non-Destructive Testing (NDT)

- 7.1 Radiography
- 7.2 Ultrasonic
- 7.3 Magnetic particles
- 7.4 Penetrating colors
- 7.5 Turbulence Flow
- 7.6 Visibility
- 7.7 Leak detection

8. Metallic and Nonmetallic Materials

8.1 Chemical, physical and engineering testing

9. Environment - Biological, Chemical, Physical and Engineering Testing

9.1 Various types of water

9.2 Waste, effluent, surface water, sea and beach water

9.3 Sludge land, solid waste and flood waters

9.4 Air including ambient air, stationary sources and work environment

9.5 Asphalts and petroleum products

10. Electricity - Electrical, Physical and Engineering Testing

10.1 Electromagnetic Compatibility (EMC)

10.2 Telephony

10.3 Product safety

11. Alcoholic Beverages

11.1 According to alcoholic beverage instructions

12. Health - Biological, Chemical and Physical Testing

12.1 Medicine

12.2 Legal medicine

12.3 Medical research

12.4 Air including ambient air, stationary sources and work environment

12.5 Noise

12.6 Agricultural products

13. Lifting Devices**14. Gas Cylinders****15. Computerized information****16. Animal Food - Biological, Chemical and Physical Testing****17. Agriculture - Diagnosis of Plant Pests, Biological, Chemical and Physical Testing****18. Animal Body Fluids and Tissues - Biological, Chemical and Physical Testing****19. Medical Products and Medical Devices - Biological, Chemical, Physical, and Engineering Testing****20. Inter-Laboratory Proficiency Testing (PT)**

ISRAC contacts' information

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Main activities during 2016

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

The total number of accredited organizations is 196.

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 have been 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 vice chair 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 2017

- 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, and 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
	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 2016 and 2017

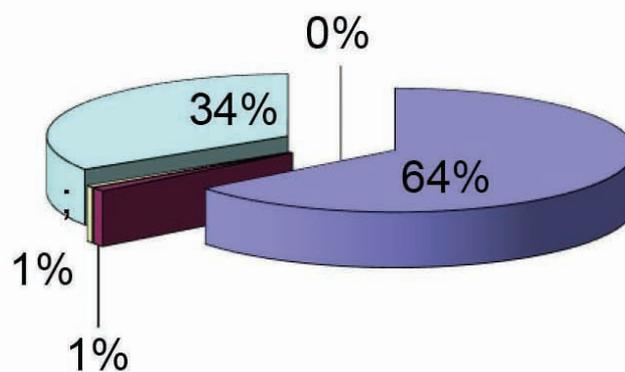
	2017 Budget NIS 000's	2016 Budget NIS 000's	Nominal Change %
Expenses			
Ongoing operation	7,066.3	6,047.9	16.8%
Open	3,243.6	3,105.1	4.5%
Total Expenses	10,309.9	9,153.0	12.6%
Activity Income			
Accreditation and supervision	6,658.4	5,288.8	25.9%
Training	120.3	78.0	54.2%
Total incomes from activities	6,778.6	5,366.8	26.3%
Funding incomes			
State budget open funding	2,800.0	2,800.0	0%
Ongoing funding from state budget			
Deficit funded from balance	681.3	936.2	-27.2%
Taxes incomes	50.0	50.0	0.00%
Total funding incomes	3,531.3	3,786.2	-6.7%
Total incomes	10,309.9	9,153.0	12.6%

Remark: developing percentages updated (relativity to previous years) according to Economy Ministry guidance.

Expenditure	2017 Budget NIS 000's	2016 Budget NIS 000's	Nominal change
Manpower	6,047.7	5,724.6	5.6%
Consultation and testing	2,462.2	1,626.9	51.3%
Office maintenance	783.0	877.4	-10.8%
more	5.0	5.0	0.0%
Total operation costs	9,297.9	8,233.8	12.9%
Deducting developing component	-2,611.7	-2,562.1	1.9%
Total on-going operation costs	6,686.2	5,671.7	17.9%
Infrastructure development	631.9	543.0	16.4%
Development Components	2,611.7	2,562.1	1.9%
Total Development	3,243.6	3,105.1	4.5%

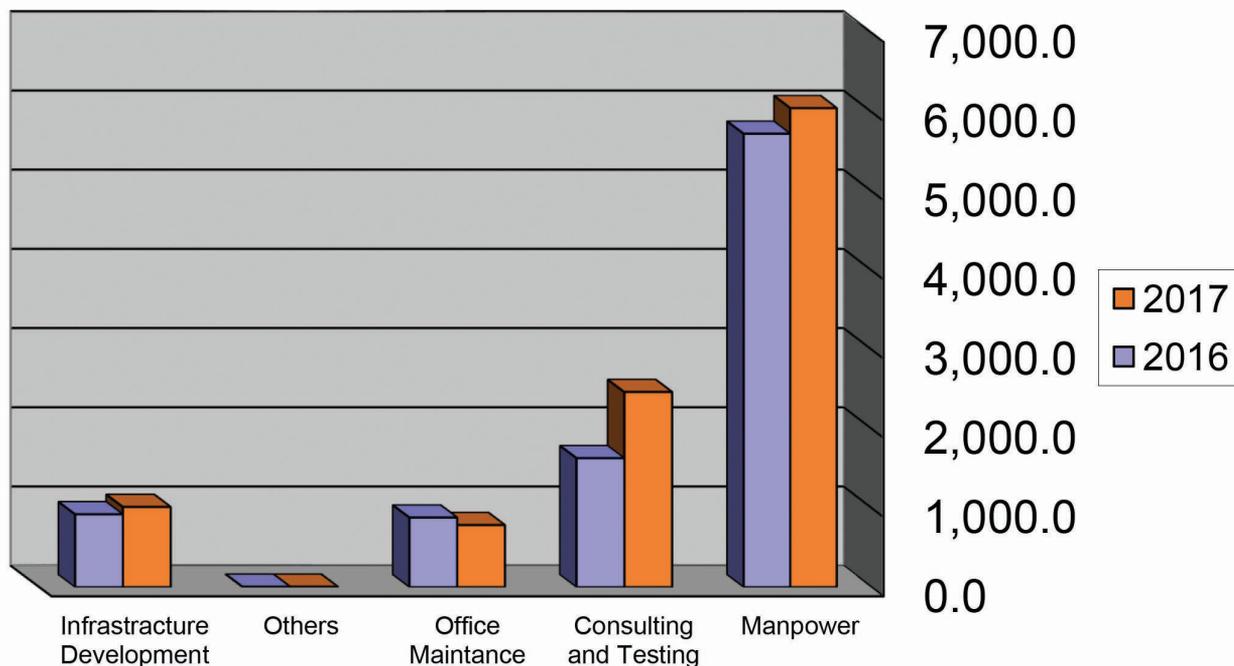
Income	2016 NIS 000's	2017 NIS 000's
GLP accreditation and assessments	5,288.8	6,658.4
Training	78.0	120.3
Interest	50.0	50.0
Open funding from state budget	2,800.0	2,800.0
Ongoing funding from state budget	0.0	0.0

2016 Income Segmentation

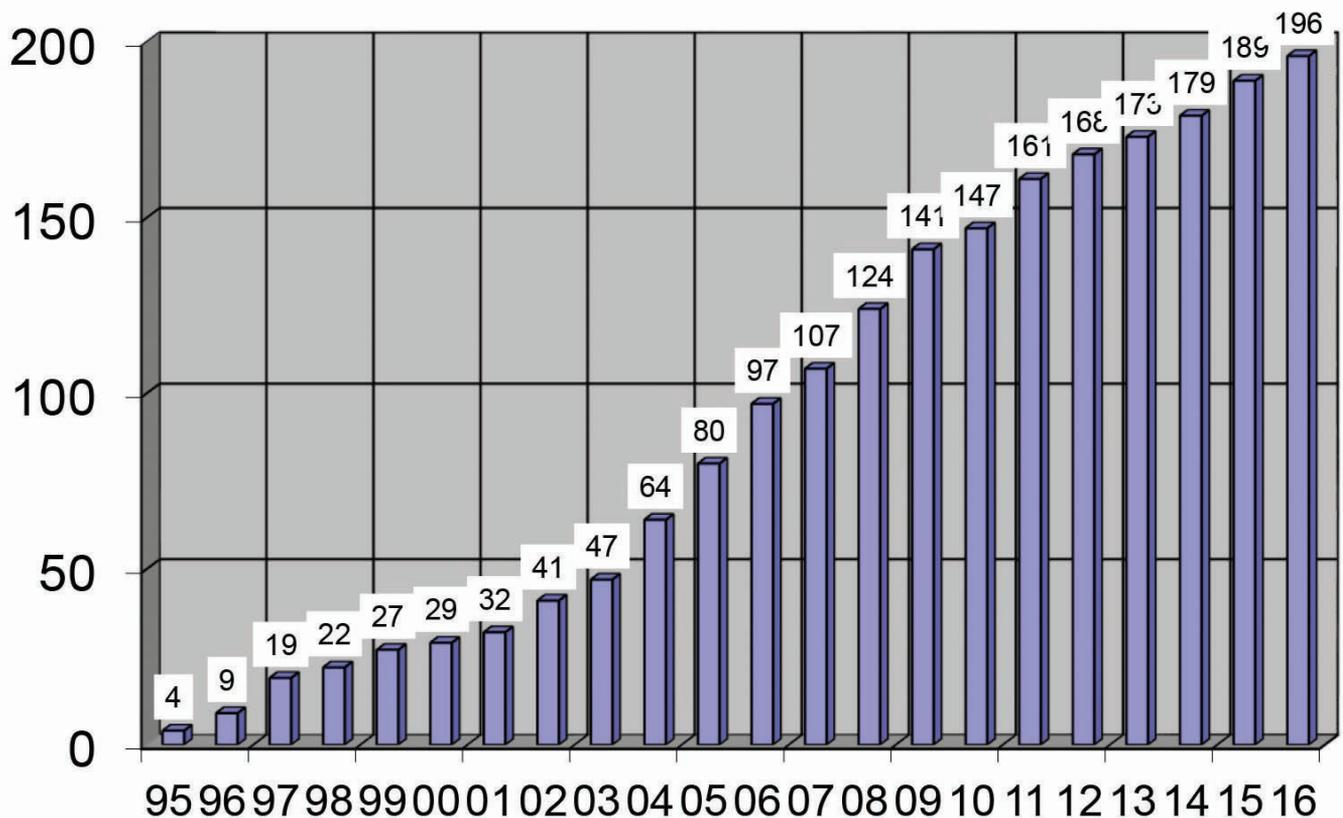


Forecast of Expenditure in 2016 budget compared with 2017 budget

	2016 NIS 000's	2017 NIS 000's
Manpower	5,724.6	6,047.7
Consulting and Testing	1,626.9	2,462.2
Office Maintance	877.4	783.0
Others	5.0	5.0
Infrastructure Development	919.2	1,012.0



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 Freedom of Information Law and publishes its activities for our clients, regulators and interested bodies over our website.

Our web site provides an updated on an ongoing basis a list of ISRAC accredited laboratories including their scope of accreditation, quarterly newsletter called 'Reshuton' published to 2500 readers, a quality manual for accreditation and recognition of GLP and accreditation needed procedures and forms. ISRAC guidelines and extensive additional information are presented bilingually (Hebrew and English).

ISRAC maintains an ongoing dialogue with its clients through meetings, courses and feedback questionnaires. ISRAC information is available for the public on demand, free of charge.

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 any 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.