



**הרשות הלאומית להסמכת מעבדות**  
**Israel Laboratory Accreditation Authority**



# **ANNUAL REPORT**

# **2017**

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## From the Chairman of Israel Laboratory Accreditation Authority

In the beginning of year 2017 I was nominated as the chairman of the Israel Laboratory Accreditation Authority, position previously held by Prof. Doron Aurbach. During this year I learned about this authority and its challenges.

The authority was established ca 20 years ago, as a national institution for ensuring high professional level of the laboratories and testing providers in Israel. These include laboratories for analytical services in the fields of medicine, engineering, chemistry, construction and agriculture. The high professional level of these labs is important for Israeli's health, safety and their high living standards. Moreover, a high level of testing in Israel is important for ensuring the quality of the locally manufactured products, and allowing for their export to many other countries. The Israel Laboratory Accreditation Authority is the only official institution for ensuring high standards of laboratories supplying various tests and calibrations. Such standards are adopted and applied in many developed countries. The authority is empowered by the state of Israel to supervise laboratories according to the OECD-GLP principles and is a full member of corresponding international organizations. The authority itself is routinely accredited by international organizations.

Although laboratory accreditation in Israel is usually in regulated areas, the authority provides services to over 250 organizations with 300 labs. Since accreditation is expensive, labs do it only when they are convinced that it is beneficial for them. They also have the choice of asking accreditation from other international authorities. Nevertheless, in the last year we have expanded the list of accredited bodies and technologies.

According to the Israeli law, the operational budget of the Israel Laboratory Accreditation Authority must

be fully covered by income from accreditations. The authority attempts to lower the accreditation cost and make its services accessible to many labs. This is done by reducing expenses and by increasing the number of accredited labs (such that the permanent costs are shared by more labs). The authority also advertises its services and initializes workshops and other educational events, in order to explain the added value due to accreditation. In spite of the high costs, the authority never compromises its high professional level and in cases where specific knowhow is not locally available, experts are invited from abroad.

Updating the Israel Laboratory Accreditation authority law is being discussed for several years and the authority management is actively involved in it. In these discussions, expanding the range of activities of the authority is considered. The new law is still under considerations and the work has not been ended yet.

Our challenges for the year 2018 include expanding our educational activities, development of new accreditation technologies and increasing the number of accredited bodies. All this, while deepening the professional level of our staff and maintaining the highest standards. We have to reach these goals in spite of expected financial restrictions.

The Israel Laboratory Accreditation Authority is run by a professional management which is guided and supervised by a council. I wish to thank the authority management for their dedicated and efficient work and the council members for their considerable investment in the authority affairs.

**Prof. Israel Schechter**

**Chairman of the Israel Laboratory Accreditation Authority.**

## From the General Manager

**2017** 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.

ISRAC has 219 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 fields of accreditation in 2016: Tests of new installation in vehicles according to the Ministry of Transport

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**

**ISRAC General Manager**



## Organizational Structure

### The Board up until December 2017

**Prof. Israel Schechter** - Chairman

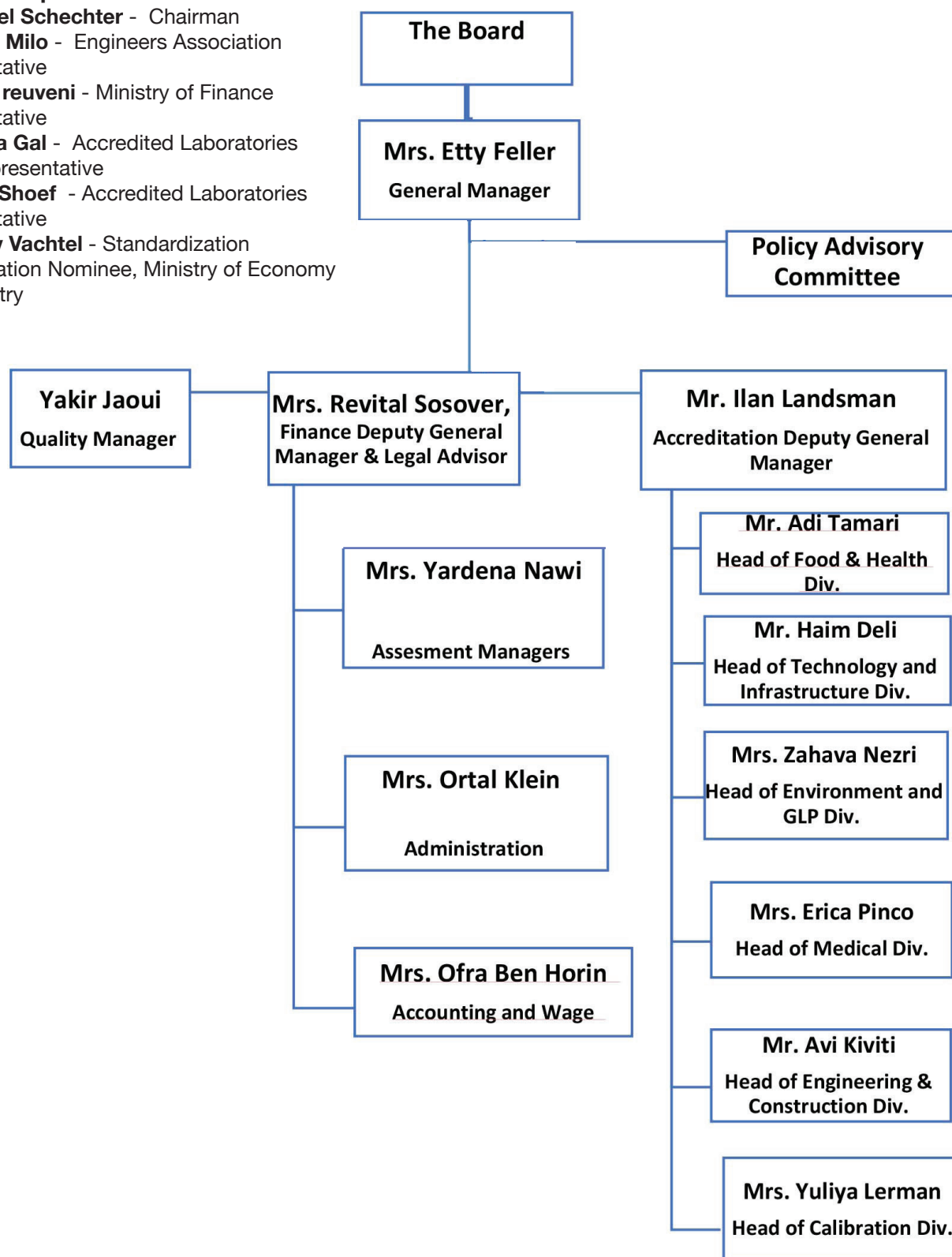
**Dr. Yakov Milo** - Engineers Association Representative

**Ms. Lidia reuveni** - Ministry of Finance Representative

**Ms. Amira Gal** - Accredited Laboratories users Representative

**Dr. Yossi Shoef** - Accredited Laboratories Representative

**Mr. Yakov Vachtel** - Standardization Administration Nominee, Ministry of Economy and Industry



\* During the year of 2017 Ms. Anna Koren, Mrs. Ravit Loitner and Ms. Shira Cohen left ISRAC

## About ISRAC

The early nineteen years were 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)****21. Transportation****22. GCLP**

## ISRAC contacts' information

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For direct correspondence with our team please see the following table:

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Head of Environmental & GLP Div.	Zahava Nezri	B.Sc.	03-9702727/203	<a href="mailto:zahavan@israc.gov.il">zahavan@israc.gov.il</a>
Head of Engineering & Construction Div.	Avi Kivity	M.Sc.	03-9702727/209	<a href="mailto:avik@israc.gov.il">avik@israc.gov.il</a>
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## Main activities during 2017

### ISRAC's law revision

Is an ongoing mission.

The Office of the Director General of the Ministry of Economy and Industry has formulated a detailed document in which we can see the need and benefit that we all have for changing the law. It will be possible to accredit in new areas and to increase enforcement in the economy. The legal bureau of the Ministry of Economics and Industry together with the Ministry of Justice and the ISRAC are working on a draft law for submission to the Knesset

### Accreditation of new laboratories

The total number of accredited organizations is 219.

Significant activity has been carried out in the area of inspection bodies in the natural gas sector and supervision of construction control institutes. There has not yet been a significant breakthrough in the number of medical laboratories in the process of accreditation despite the great potential in this field. A large number of extension assessments were conducted to expand the activity of the 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 2018

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

## Budget for 2017 and 2018

	2017 Budget NIS 000's	2018 Budget NIS 000's	Nominal Change %
<b>Expenses</b>			
Regular operation	7,066.3	6,785.7	-4.0%
Development	3,243.6	3,114.3	-4.0%
<b>Total Expenditure</b>	<b>10,309.9</b>	<b>9,899.9</b>	<b>-4.0%</b>
<b>Income from Operations</b>			
Accreditation and surveillance	6,658.4	6,987.1	4.9%
Training	120.3	65.0	-45.9%
<b>Total incomes from Operations</b>	<b>6,778.6</b>	<b>7,052.1</b>	<b>4%</b>
<b>Income from Funding</b>			
Funding of development from state budget	2,800.0	2,800.0	0%
Regular funding from state budget	0.0	0.0	
Financed balance deficit	681.3	-2.2	-100.3%
Interest incomes	50.0	50.0	0.00%
<b>Total income financed</b>	<b>3,531.3</b>	<b>2,847.8</b>	<b>-19.4%</b>
<b>Total income</b>	<b>10,309.9</b>	<b>9,899.9</b>	<b>-4.0%</b>

Remark:

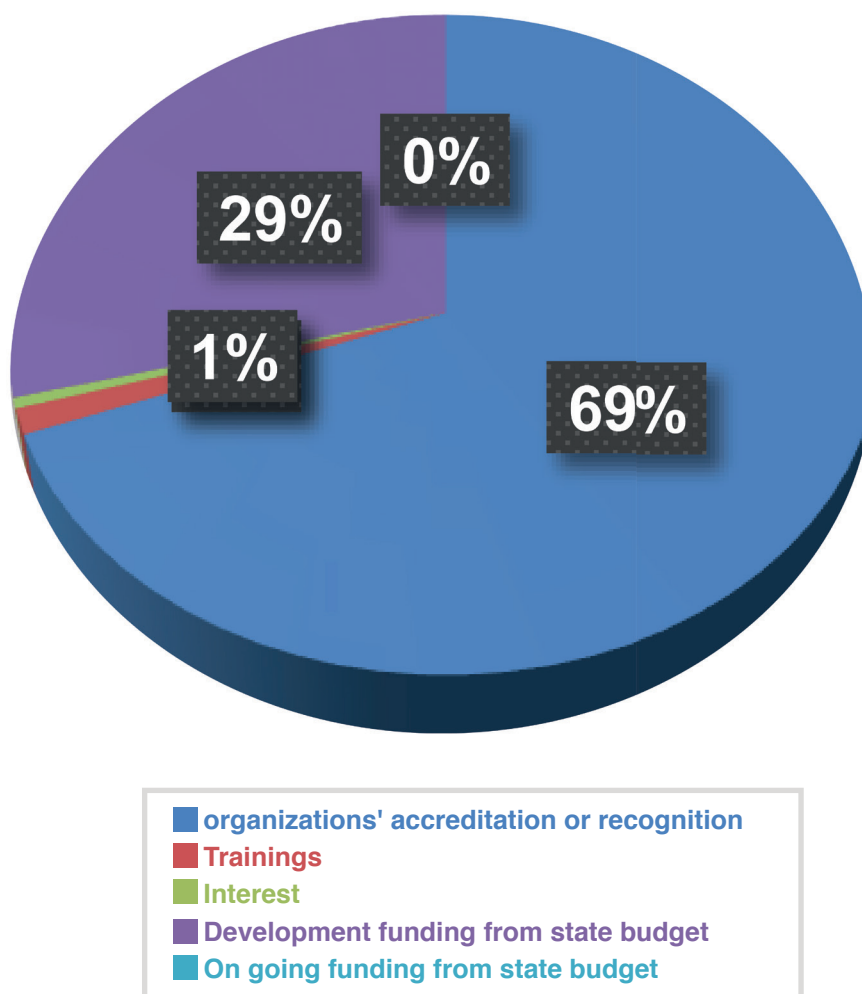
Development rates have been updated in accordance with the instructions of the Ministry of Economy and Industry.

Expenditure	2017 Budget NIS 000's	2018 Budget NIS 000's	Nominal change
Personel	6,047.7	5,912.4	-2.2%
Consultation and testing	2,462.2	2,108.0	-14.4%
Office maintenance	783.0	778.9	-0.5%
Other	5.0	5.0	0.0%
<b>Total operating Expenditure</b>	<b>9,297.9</b>	<b>8,804.3</b>	<b>-5.3%</b>
Development Element	-2,611.7	-2,489.2	-4.7%
<b>Total regular operation</b>	<b>6,686.2</b>	<b>6,315.1</b>	<b>-5.6%</b>
Infrastructure	631.9	625.0	-1.1%
Development Components	2,611.7	2,489.2	-4.7%
<b>Total Development</b>	<b>3,243.6</b>	<b>3,114.3</b>	<b>-4.0%</b>



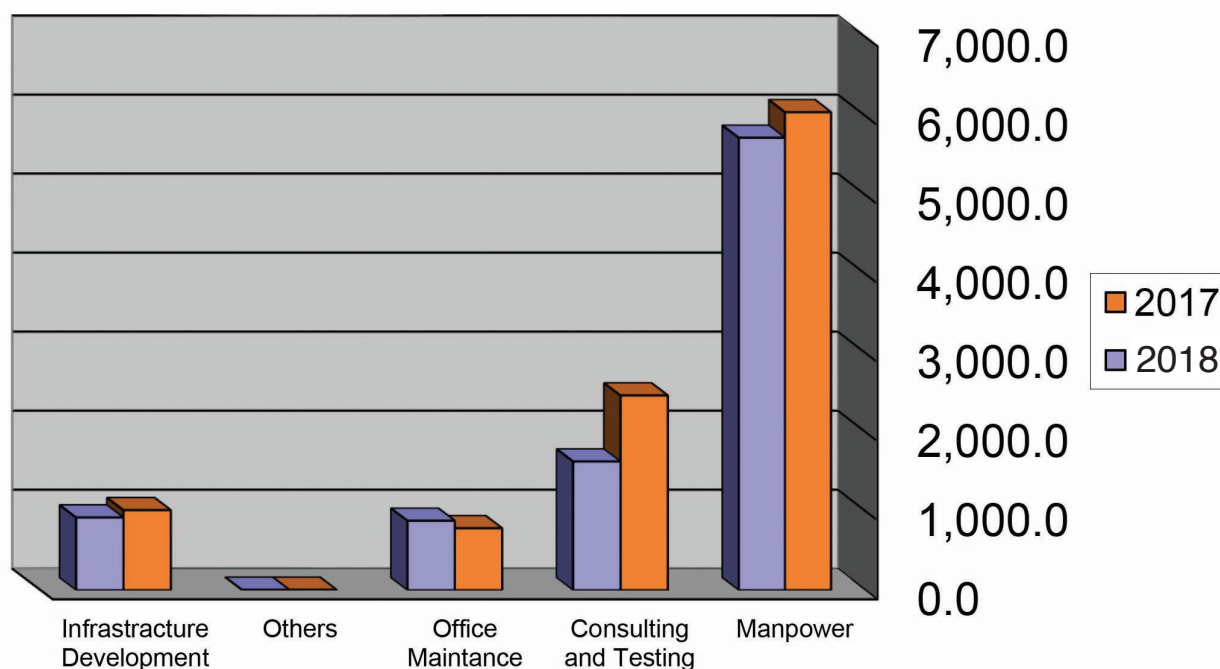
Income	2017 NIS 000's	2018 NIS 000's
Organization's accreditation or recognition	6,658.4	6,987.1
Training	120.3	65.0
Interest	50	50
Development funding from state budget	2,800.0	2,800.0
On going funding from state budget	0.0	0.0

## 2017 Revenue distribution

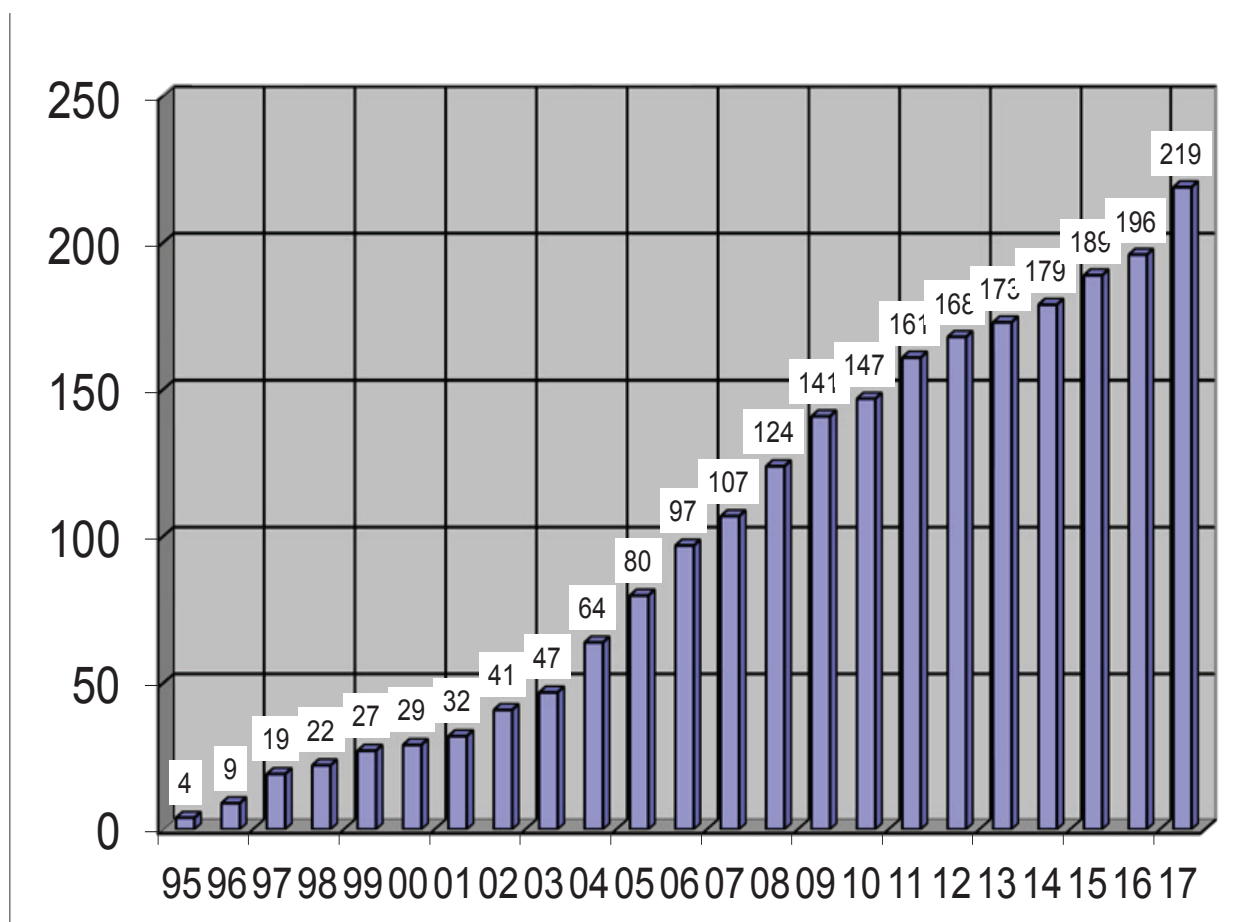


## Forecast of Expenditure in 2016 budget compared with 2017 budget

	2018 NIS 000's	2017 NIS 000's
Manpower	5912.4	6,047.7
Consulting and Testing	2,108.0	2,462.2
Office Maintenance	778.9	783.0
Others	5.0	5.0
Infrastructure Development	1,095.6	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.