



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



# **ANNUAL REPORT**

# **2018**

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## From the Chairman of Israel Laboratory Accreditation Authority

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 270 organizations with 330 labs. Since accreditation cost labs will join voluntary 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 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 2019 include expanding our educational activities, development of new accreditation technologies and increasing the number of accredited bodies and we hope to get an extension in our law to include accreditation of certification 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

The year 2018 marked a significant change in the work processes of Israel Laboratory Accreditation Authority. In the first part of the year, ISRAC's work procedures were adapted to meet the requirements of the updated international standards, ISO / IEC 17011 2017 and ISO / IEC 17025 2017. These changes were followed by assessors and laboratory training as well as internal audits to ensure implementation of the changes. As a function of ISRAC's work with the regulators, new guidance documents for accreditation were written and requirements for accreditation in accordance with the country's laws were updated. New accreditation for inspection bodies in the fields of natural gas and supervision of construction in Israel were initiated.

The situation at the end of 2018:

The Israel Laboratory Accreditation Authority has 246 accredited organizations.

During the year, the scope of accreditation of several organizations was expanded and a dozen new technologies was added. New areas of accreditation were added as a result of the activities of the ISRAC team with regulators and interested parties. 33 new organizations were accredited, and the accreditation of six organizations have been withdrawn.

As stated, the ISRAC staff expanded its cooperation with various regulators. This cooperation provides the regulators with a tool to monitor the laboratories working in their respective fields without being a burden on their current activities and annual budgets, especially those who use the accreditation services as part of the approval or recognition requirements.

The advisory committee for the Director-General of the ISA met twice this year. These meetings enable discussions about new areas in which it is possible to develop the Authority's activities.

An international assessment to examine the extent to which the requirements of the updated international standard for ISO / IEC 17011 2017 are implemented

was performed on May 2018. The conclusion of the team was that the activities of ISRAC are in full accordance with international law requirements and regulations.

At the ILAC General Assembly in October 2018, the Director General of ISRAC Mrs. Etty Feller was elected as the Chairman of ILAC. A choice that indicates professional esteem and trust.

ISRAC is the representative of the State of Israel for supervision in accordance with the OECD-GLP principles. ISRAC was accepted as a full member of the OECD-GLP working group since 2004.

In the matter of the Authority Law, the Memorandum of the Law of the Authority passed its first reading in the Knesset and was referred to the Knesset Economics Committee.

Throughout the year, ISRAC staff devoted their energies to improving the varied online training program for accredited organizations personnel and ISRAC-employed assessors.

I would like to thank all ISRAC employees for their effort and willingness to work tirelessly in the various fields of ISRAC activity and for meeting all the international requirements for accreditation organizations.

We have been working since 1997 to advance the Authority's mandate  
"Promoting the quality and professional competence of calibrating / testing bodies harmonizing with the world for the benefit of the state and its citizens"

I would like to thank the regulators who use ISRAC accreditation as part of their enforcement processes for which they are entrusted, to the stakeholders and to our customers, for the trust they have given and are giving to the Authority's activities.

**Etty Feller**  
**General Manager, ISRAC**  
**Israel Laboratory**  
**Accreditation Authority**



## Organizational Structure

The composition of ISRAC Council until 12.2018

Prof. Israel Schechter - Chairman

Dr. Yaakov Milo - representative of the Engineers and Architects Association

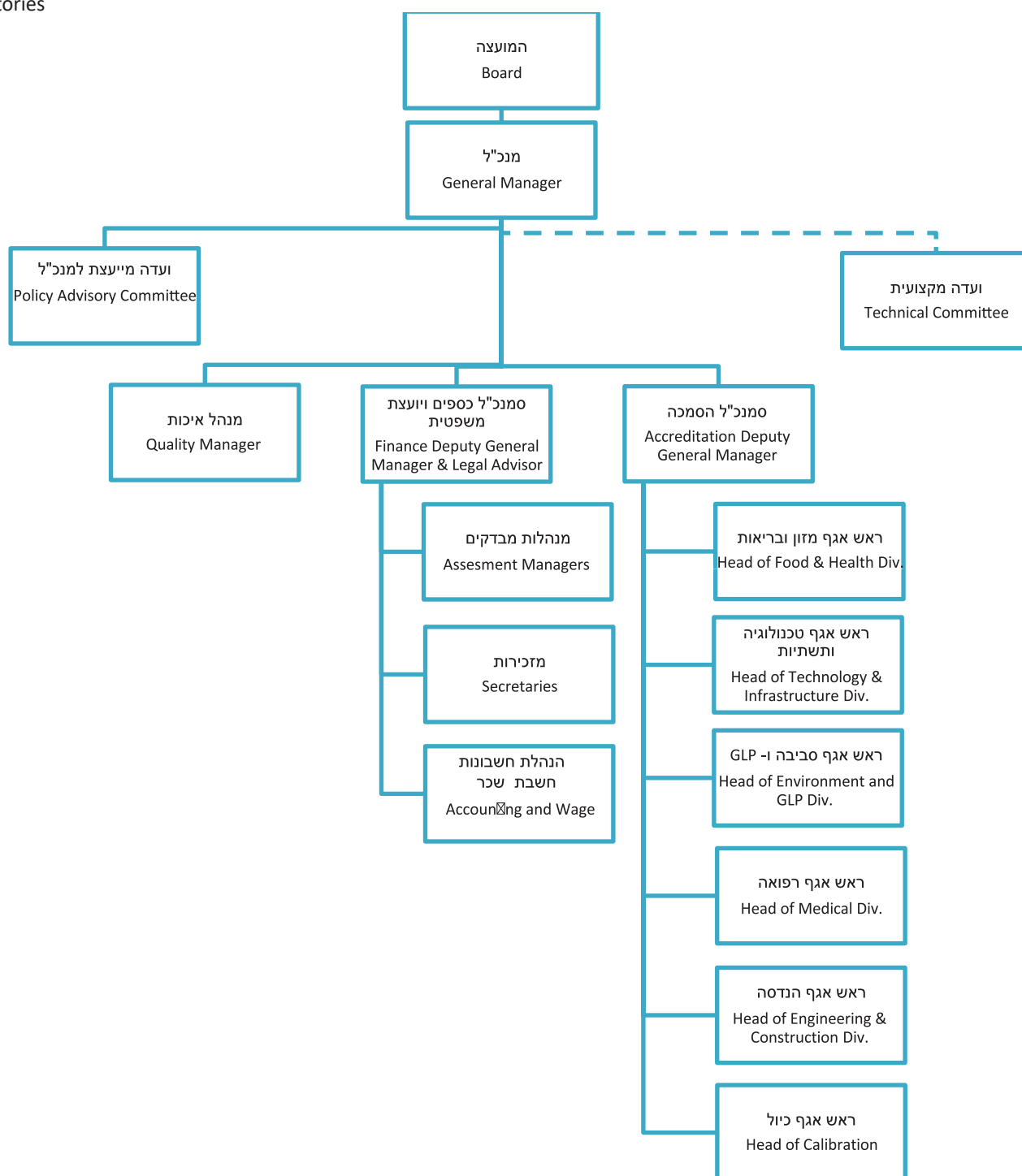
Ms. Lydia Reuveni - Representative of the Ministry of Finance

Ms. Amira Gal - representative of the users of the laboratory services

Dr. Yossi Shoem - Representative of the accredited laboratories

Mr. Jacob Wachtel - Commissioner of Standardization, Ministry of Economy and Industry

Dr. Michael Shandlov - Representative of the accredited laboratories



## About ISRAC

During the early nineties the awareness for the importance of ensuring product quality and compliance with national or international standards was on the rise both in Israel and around the world.

The purpose of these standards is first and foremost 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 others, an international accreditation system is required for 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 restricting standardization. The accreditation bodies in industrialized countries 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 enable the authorities and government ministries to grant judicial validity to the tests performed at laboratories that have received their recognition. For example, the Standards Law, (1953) enables the Standards supervisor of the Ministry of Industry and Trade (today called Ministry of Economy and Industry) to designate 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 that statement, 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 of 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, guidance and the dissemination of related information.

## What is a laboratory accreditation?

Accreditation of a laboratory acts as an official recognition of its 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.

### Important Information!

**Accreditation provides formal recognition of the organization's abilities and its employee professional competence and therefore acts as a guarantee for large consumers and clients like enforcement authorities of reliable and quality service for testing, measurement and calibrations.**

## ISRAC's International Activities: Outline and Ramifications

### Accreditation

ISRAC is a full 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 2001, ISRAC was recognized by ILAC and by the EA (European Accreditation - European regional organization). ISRAC has signed the ILAC mutual recognition arrangement (MRA).

The MRA provides recognition by the accreditation bodies of 100 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 –EA. . 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 in gaining confidence in the analysis results that its products undergo.

In 2018, 17 pre-clinical research facilities were 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.

### 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.



## 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.

### 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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Email: [israc@israc.gov.il](mailto:israc@israc.gov.il), Website: [www.israc.gov.il](http://www.israc.gov.il)

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

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Accreditation Deputy General Manager	Ilan Landesman	BA, CQE	03-9702727/219	<a href="mailto:ilanl@israc.gov.il">ilanl@israc.gov.il</a>
Quality Manager	Yakir Jaoui	B.Sc., MBA	03-9702727/212	<a href="mailto:yakirj@israc.gov.il">yakirj@israc.gov.il</a>
Head of Medical Div.	Ori Elad	Phd.	03-9702727/204	<a href="mailto:orie@israc.gov.il">orie@israc.gov.il</a>
Head of Environmental & GLP Div.	Zahava Nezri	B.Sc.	03-9702727/203	<a href="mailto:zahavan@israc.gov.il">zahavan@israc.gov.il</a>
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Assessment Manager	Yardena nawi	BA	03-9702727/226	<a href="mailto:yardena@israc.gov.il">yardena@israc.gov.il</a>
Secretary	Ortal Shiro		03-9702727/213	<a href="mailto:ortals@israc.gov.il">ortals@israc.gov.il</a>
Wage and Accountant Manager	Ofra Ben Horin		03-9702727/209	<a href="mailto:ofrab@israc.gov.il">ofrab@israc.gov.il</a>



## Main activities during 2018

### Seeking approval for ISRAC's law revision is an ongoing mission.

The Director General of the Ministry of Economy and Industry has formulated a detailed document that describes the need and benefit for changing the law clearly. It will be possible to accredit laboratories in new fields and to increase enforcement in the economy. The legal bureau of the Ministry of Economics and Industry together with the Ministry of Justice and ISRAC are working on a draft law for submission to the Knesset

The Director General of the Ministry of Economy and Industry has submitted the memorandum of the law to the Knesset. The document passed the first reading and was submitted for deliberation at the Knesset Economy committee.

### Accreditation of new laboratories

The total number of accredited organizations is 246.

Significant activity has been carried out in the area of inspection bodies in the natural gas sector and supervision of construction control institutes. 33 new organizations were accredited throughout 2018. There has yet to be significant progress in the number of medical laboratories going through 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 as 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 2019

- Approval of ISRAC law.
- Increasing the number of accredited organizations and increasing the scope of accredited laboratories.
- Organizing professional training for improving quality procedures and professional conduct in accredited organizations.
- Developing new areas and expanding on existing 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. Implementation of the requirement for ISRAC accreditation on other laws.
- Cooperation with international accreditation and standardization organizations.

## Cooperation regulators

Government office	Activity fieldw	Requires accreditation	Accredited office labs
<b>Health</b>	Water and food	Yes	None
	Clinical labs	No	None
<b>Agriculture</b>	Pesticides	No	Yes
	Pesticides residue	Yes	Yes
	Plant diseases	Yes	Partial
	veterinarian Services	Partial	Partial
<b>Defense</b>	All areas	Yes	No
<b>Economic</b>	Standards	Yes	No
	supervisor	No	No
	Radiation	Yes	No
	Hygiene	Yes	Yes
	Noise	In process	No
	Diamond inspector	-	-
<b>Environment</b>	Radiation	In process	No
	Soil, Sewage, Fuel	In partial	No
	Air Quality	In process	No
	Pesticides	-	-
<b>Infrastructure</b>	Fuel	Yes	No
	Water meters	Yes	No
	Water quality	No	
	Sewage and water	Yes	No
<b>Transportation</b>	Cars	No	No
	Car devices	Yes	No
<b>Building and occupation</b>	Building	Yes (except SII)	No
<b>Interior defense</b>	Forensic	No	Yes
	Transportation police	Yes	Yes

## Budget for 2018 and 2019

	2018 Budget NIS 000's	2019 Budget NIS 000's	Nominal Change %
<b>Expenses</b>			
Regular operation	6,785.7	7,470.3	10.1%
Development	3,114.3	3,172.1	1.9%
<b>Total Expenditure</b>	<b>9,899.9</b>	<b>10,642.4</b>	<b>7.5%</b>
<b>Income from Operations</b>			
Accreditation and surveillance	6,987.1	7,765.2	11.1%
Training	65.0	68.3	5.0%
<b>Total incomes from Operations</b>	<b>7,052.1</b>	<b>7,833.5</b>	<b>11.1%</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	-2.2	0.0	-98.9%
Interest incomes	50.0	9.0	-82.0%
<b>Total income financed</b>	<b>2,847.8</b>	<b>2,809.0</b>	<b>-1.4%</b>
<b>Total income</b>	<b>9,899.9</b>	<b>10,642.4</b>	<b>7.5%</b>

Remark:

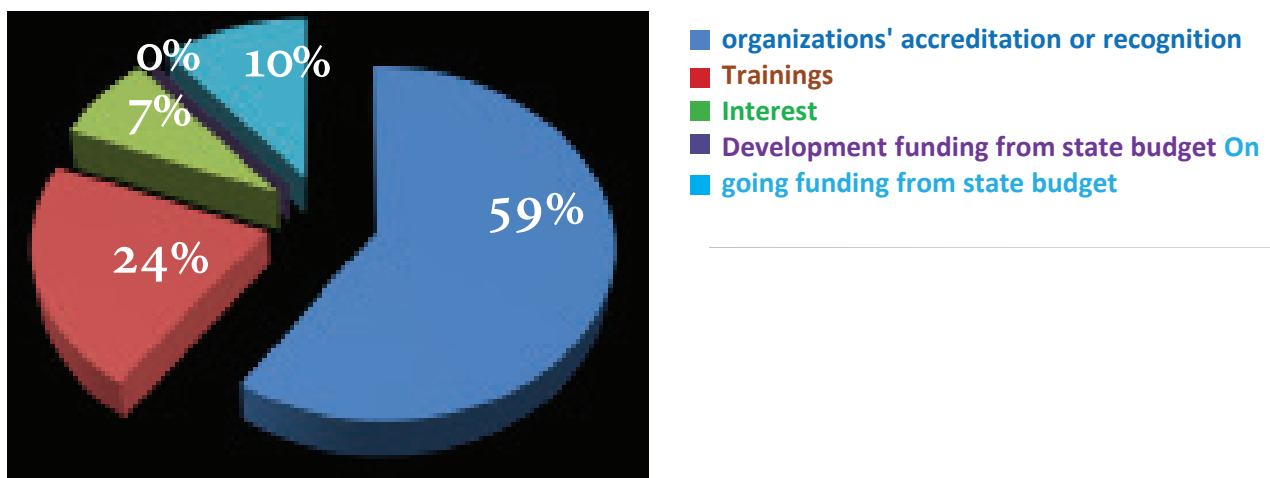
Development rates have been updated in accordance with the instructions of the Ministry of Economy and Industry.

Expenditure	2018 Budget NIS 000's	2019 Budget NIS 000's	Nominal change
Personel	5,912.4	6,020.0	1.8%
Consultation and testing	2,108.0	2,869.8	36.1%
Office maintenance	778.9	775.7	-0.4%
Other	5.0	5.0	0.0%
<b>Total operating Expenditure</b>	<b>8,804.3</b>	<b>9,670.6</b>	<b>9.8%</b>
Development Element	-2,489.2	-2,688.5	8.0%
<b>Total regular operation</b>	<b>6,315.1</b>	<b>6,982.1</b>	<b>10.6%</b>
Infrastructure	625.0	483.6	-22.6%
Development Components	2,489.2	2,688.5	8%
<b>Total Development</b>	<b>3,114.3</b>	<b>3,172.1</b>	<b>1.9%</b>

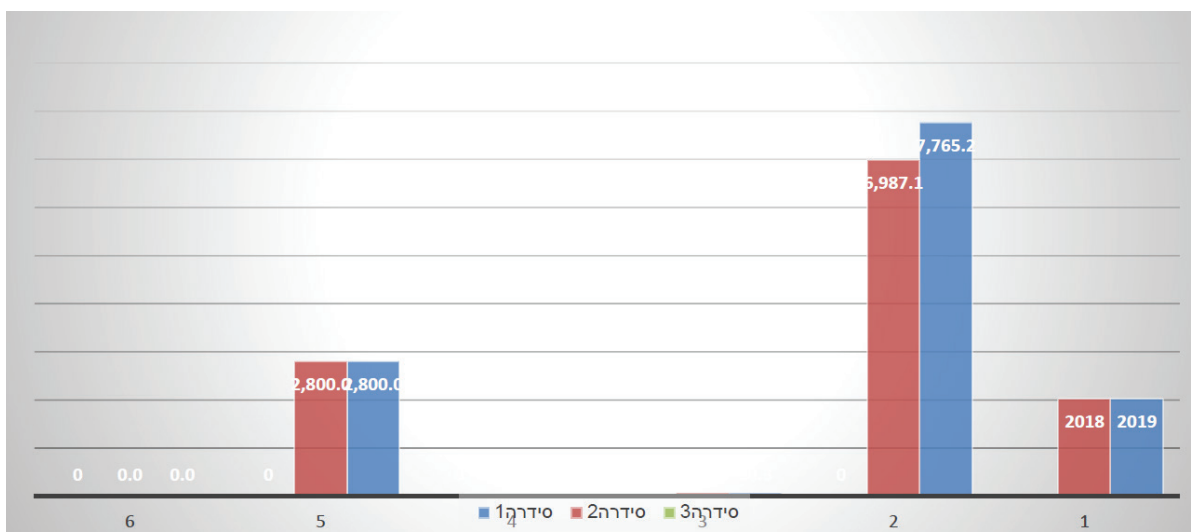


Income	2018 NIS 000's	2019 NIS 000's
organization's accreditation or recognition	6,987.1	7,765.2
Training	65.0	68.3
Interest	50.0	9.0
Development funding from state budget	2,800.0	2,800.0
on going funding from state budget	0.0	0.0

## 2018 Revenue distribution

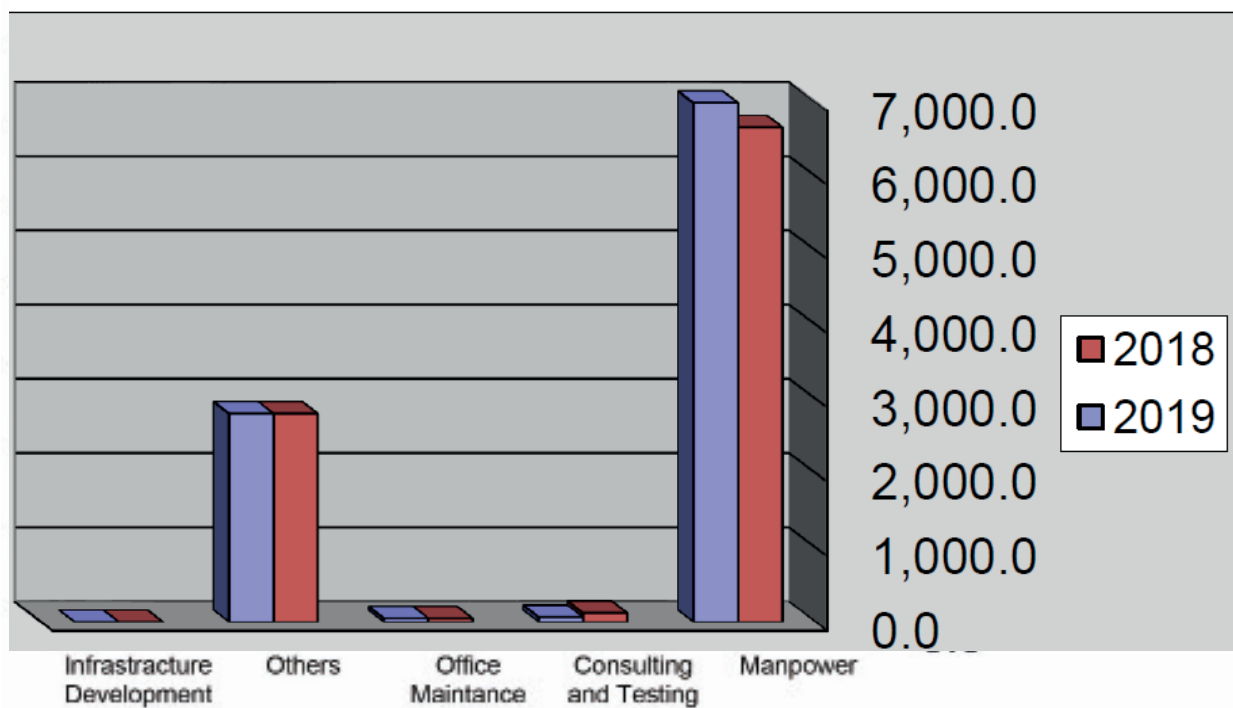


## Forecast of Expenditure in 2018 budget compared with 2019 budget

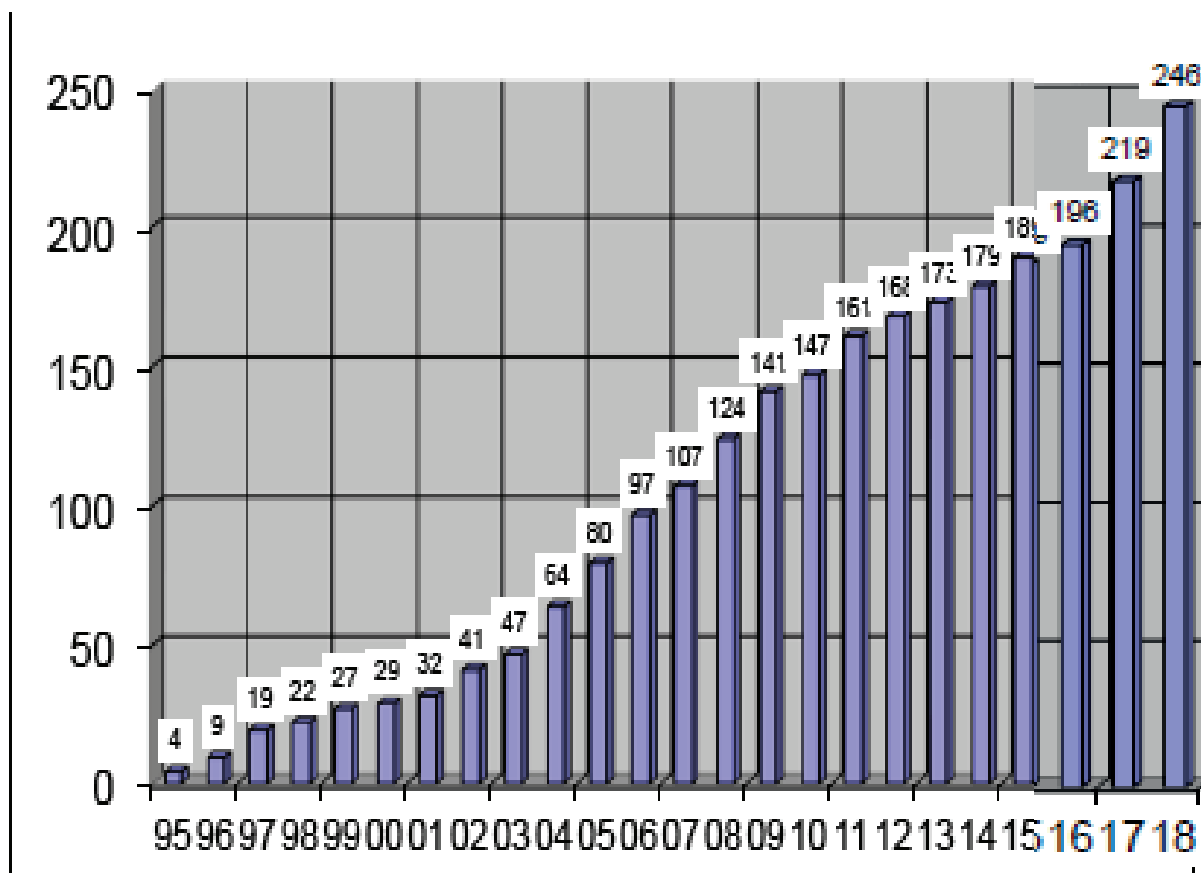


## Forecast of Expenditure in 2019 budget compared with 2018 budget

	2018 NIS 000's	2019 NIS 000's
Manpower	5,912.4	6,020.0
Consulting and Testing	2,108.0	2,869.8
Office Maintenance	778.9	775.7
Others	5.0	5.0
Infrastructure Development	1,095.6	976.8



## 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.