



הרשות הלאומית להסמכת מעבדות
Israel Laboratory Accreditation Authority



ANNUAL REPORT

2019

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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 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 2020 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 2019 implementation of the significant changes in the work processes of Israel Laboratory Accreditation Authority was considered. Approximately 50% of accredited organizations have implemented the updated standard ISO / IEC 17025 2017. Updates which required the adaptation of work procedures management procedures and implementation of root causes investigations processes for findings and risk assessment. The work with the regulators was maintained as guidance documents for accreditation and updating requirements for accreditation according to the country's laws. New accreditation for inspection bodies in the natural gas field and supervision of construction in Israel were initiated.

The situation at the end of 2019:

The Israel Laboratory Accreditation Authority has 266 accredited organizations.

During the year, scope of accreditation was expended and a dozen new technologies were expanded. New areas of accreditation were added as a result of the activities of the ISRAC team with regulators and interested parties. 30 new organizations were accredited, and the accreditation of 10 organizations has been withdrawal. The ISRAC staff expanded its cooperation with various regulators. This cooperation provides the regulators with a tool to monitor their activities 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. During the year, an advisory committee met twice a year for the Director-General of the ISRAC, enabling us to learn about new areas in which it is possible to develop the Authority's activities

The Israel Laboratory Accreditation Authority (ISRAC) is the representative of the State of Israel for supervision in accordance with the OECD-GLP principles. ISRAC is 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.

During the year, ISRAC staff devoted their energies to improving the varied online training program for the staff of accredited organizations.

Thank you to all employees of ISRAC for the effort and willingness to work tirelessly in the various fields of activity of ISRAC Authority and to meet all the international requirements required of 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".

Thank you to the regulators who use ISRAC accreditation as part of the enforcement processes for which they are entrusted, to the stakeholders and to our customers, for the trust they have given and to give to the Authority's activities.

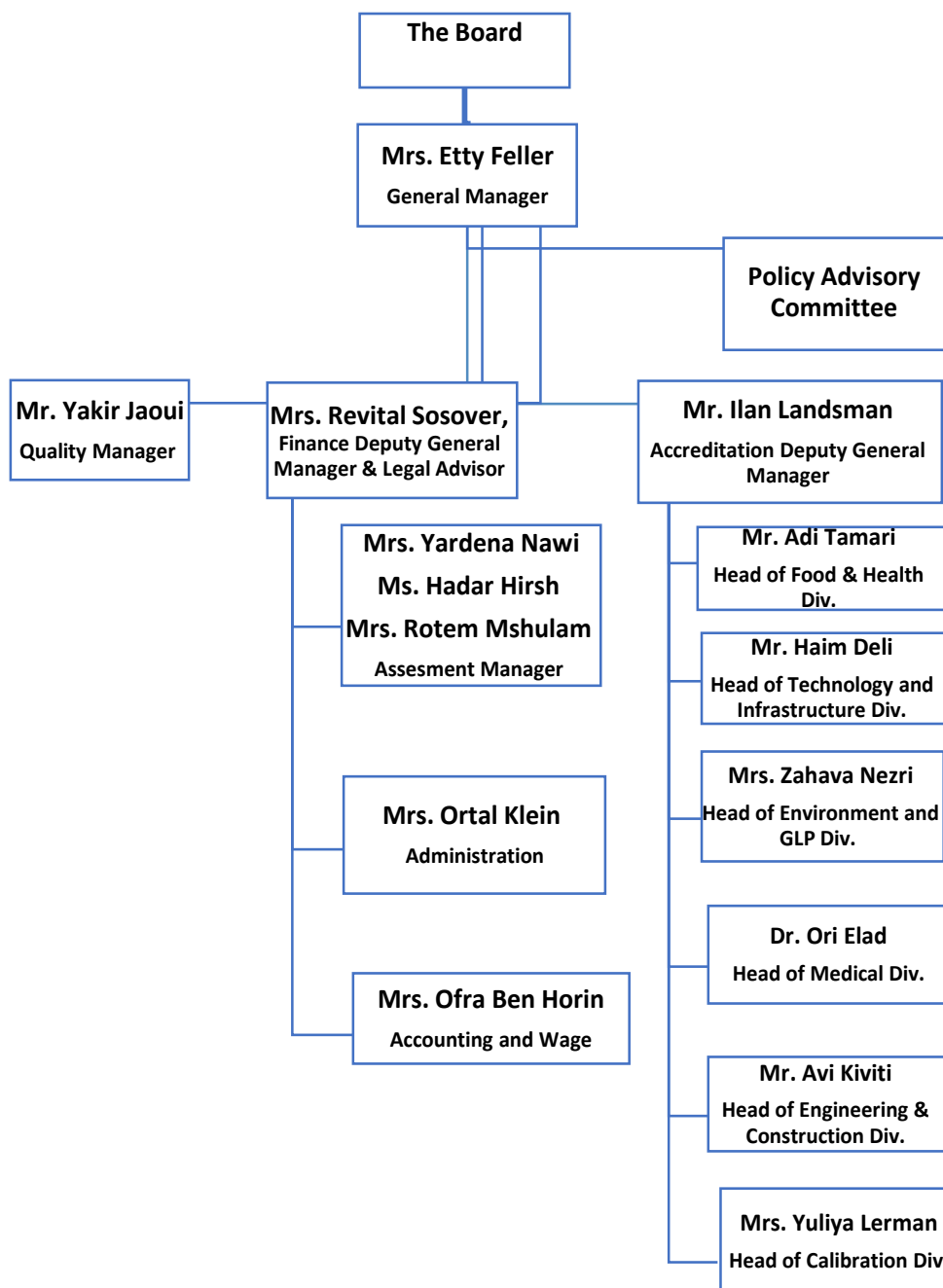
Etty Feller

ISRAC General Manager

Organizational Structure

The composition of ISRAC Council until 12.2019

- 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
- Mr. Jacob Wachtel - Commissioner of Standardization, Ministry of Economy and Industry
- Dr. Michael Shandlov - Representative of the accredited laboratories



About ISRAC

The early nineties were characterized by increasing awareness in Israel and around the world for 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 is 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 laboratories accreditation.

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 the 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.

Important Information!

Accreditation provides formal recognition for organizations' ability and employee professional competence and is therefore a means to large consumers 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 for any test or calibration performed by a laboratory accredited by ISRAC recognition by the accreditation bodies of 102 countries that have already signed MRAs. 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 of 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 the recognition that they operate in accordance with the GLP principles.

ISRAC conducts assessments under the directives of the OECD, EPA, and FDA.

In 2019, 20 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 ISRAC staff, 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 floodwaters

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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Accreditation Deputy General Manager	Ilan Landesman	BA, QE	03-9702727/219	ilanl@israc.gov.il
Quality Manager	Yakir Jaoui	B.Sc., MBA	03-9702727/212	yakirj@israc.gov.il
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Main activities during 2019

Seeking approval to revise ISRAC's law

The Minister of Economy and Industry, who authorizes in the Knesset the Memorandum of ISRAC Law, the next step will be discussed by the Knesset Economics Committee in parallel, ISRAC with the Ministry of Economy and Industry and the Ministry of Justice, working to improve the proposal.

Accreditation of new laboratories

A total of 262 accredited/recognized organizations.

Twenty-four new organizations have been accredited during the year 2019. No significant breakthroughs have yet been made in the number of medical laboratories in the process of accreditation despite the great potential in this area due to the fact that no regulator's decision to require accreditation as part of the risk management process. A large number of scope expansion accreditation was conducted among 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 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 2020

- Approval of ISRAC law.
- Increasing the number of accredited organizations and increasing the scope of accredited laboratories.
- Increasing the use of online courses to 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 field	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	Yes	Partial	
	Services			
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	In process	No	
	infrastructure			
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 2019 and 2020

	2019 Budget NIS 000's	2020 Budget NIS 000's	Nominal Change %
Expenses			
Regular operation	7,470.3	7,498.8	0.4%
Development	3,172.1	3,147.3	-0.8%
Total Expenditure	10,642.4	10,646.0	0.0%
Income from Operations			
Accreditation and surveillance	7,765.2	7,755.6	-0.1%
Training	68.3	60.5	-11.4%
Total incomes from Operations	7,816.1	7,816.5	-0.2%
Income from Funding			
Funding of development from state budget	2,800.0	2,800.0	0%
Regular fundung from state budget			
Financed balance deficit	0.0	0.0	-46.1%
Interest incomes	9.0	30.0	-233.3%
Total income financed	2,809.0	2,830.0	0.7%
Total income	10,642.4	10,646.0	0.0%

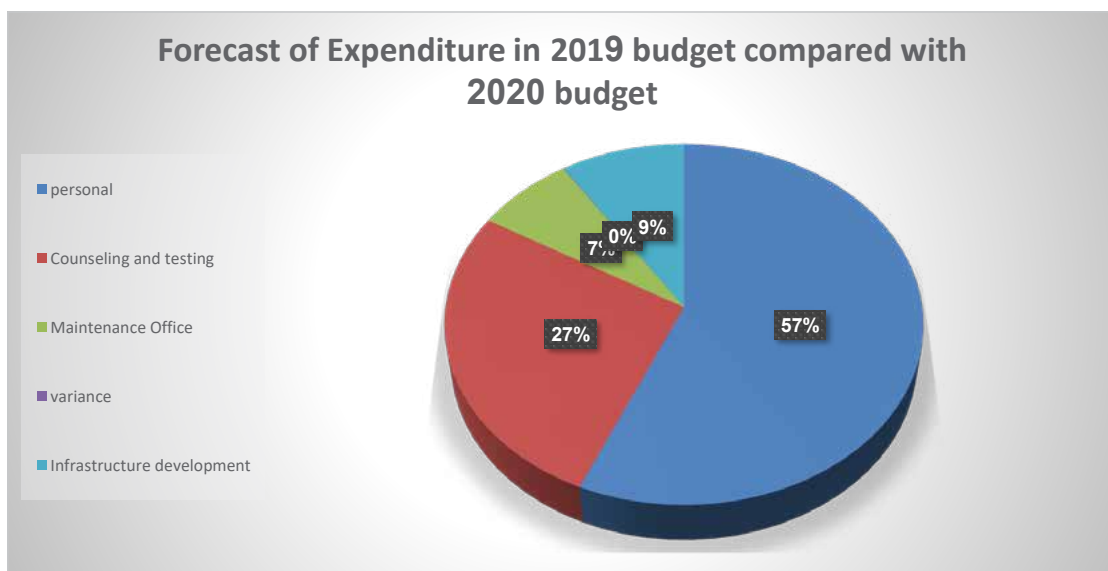
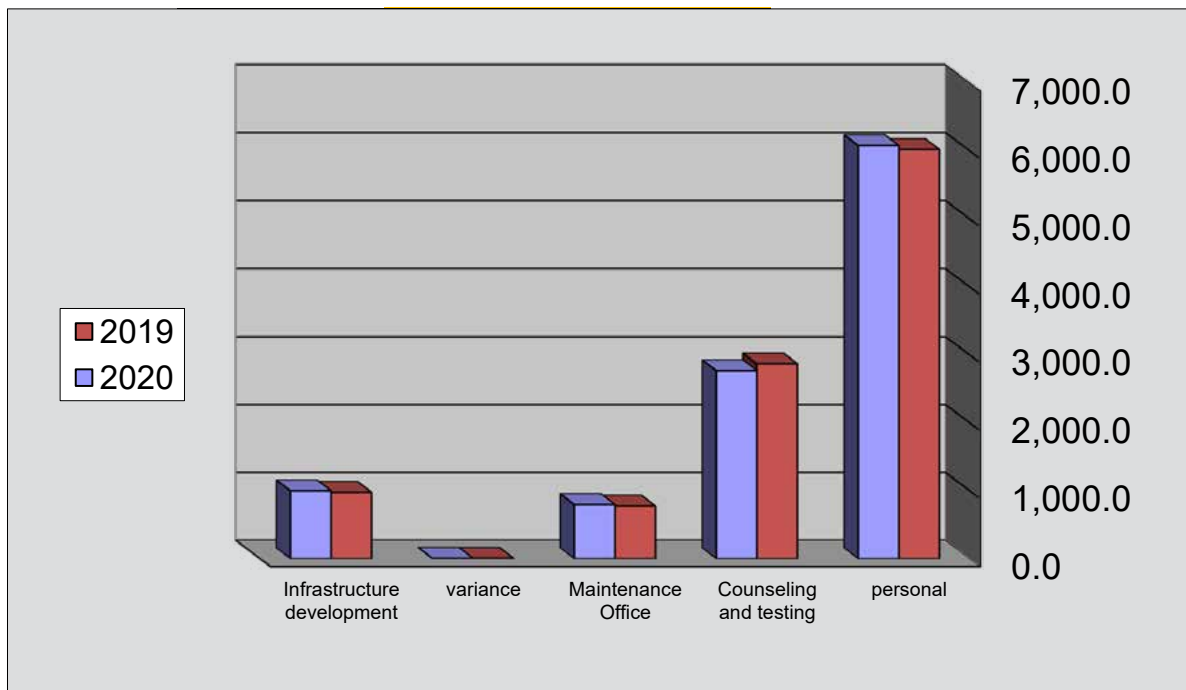
Remark:

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

Expenditure	2019 Budget NIS 000's	2020 Budget NIS 000's	Nominal change
Personel	6,020.0	6,079.0	1.0%
Consultation and testing	2,869.8	2,769.2	-3.5%
Office maintenance	775.7	797.8	2.8%
Other	5.0	5.0	-0.0%
Total operating Expenditure	9,670.6	9,650.9	-0.2%
Development Element	-2,688.5	-2,659.5	-1.1%
Total regular operation	6,982.1	6,991.4	0.1%
Infrastructure	483.6	487.8	0.9%
Development Components	2,688.5	2,659.5	-1.1%
Total Development	3,172.1	3,147.3	-0.8%

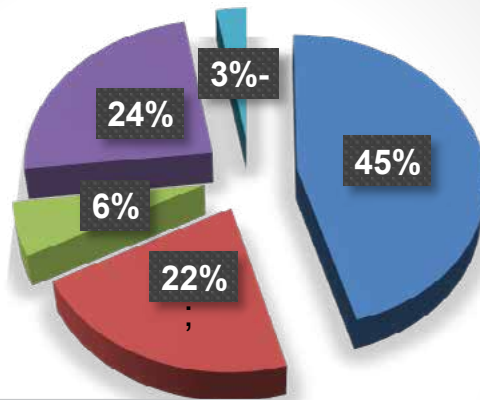
Forecast of Expenditure in 2020 budget compared with 2019 budget

	2019 NIS 000's	2020 NIS 000's
personal	6,020	6,079.0
Counseling and testing	2,869.8	2,2769.2
Maintenance Office	775.7	797.8
variance	5	5
Infrastructure development	976.8	1000.1



Income	2019 NIS 000's	2020 NIS 000's
organizations' accreditation or recognition	7,765.2	7,755.6
Training	68.3	60.5
Interest	9	30
Development funding from state budget	3,172.1	3,147.3
on going funding from state budget	-372.1	-347.3

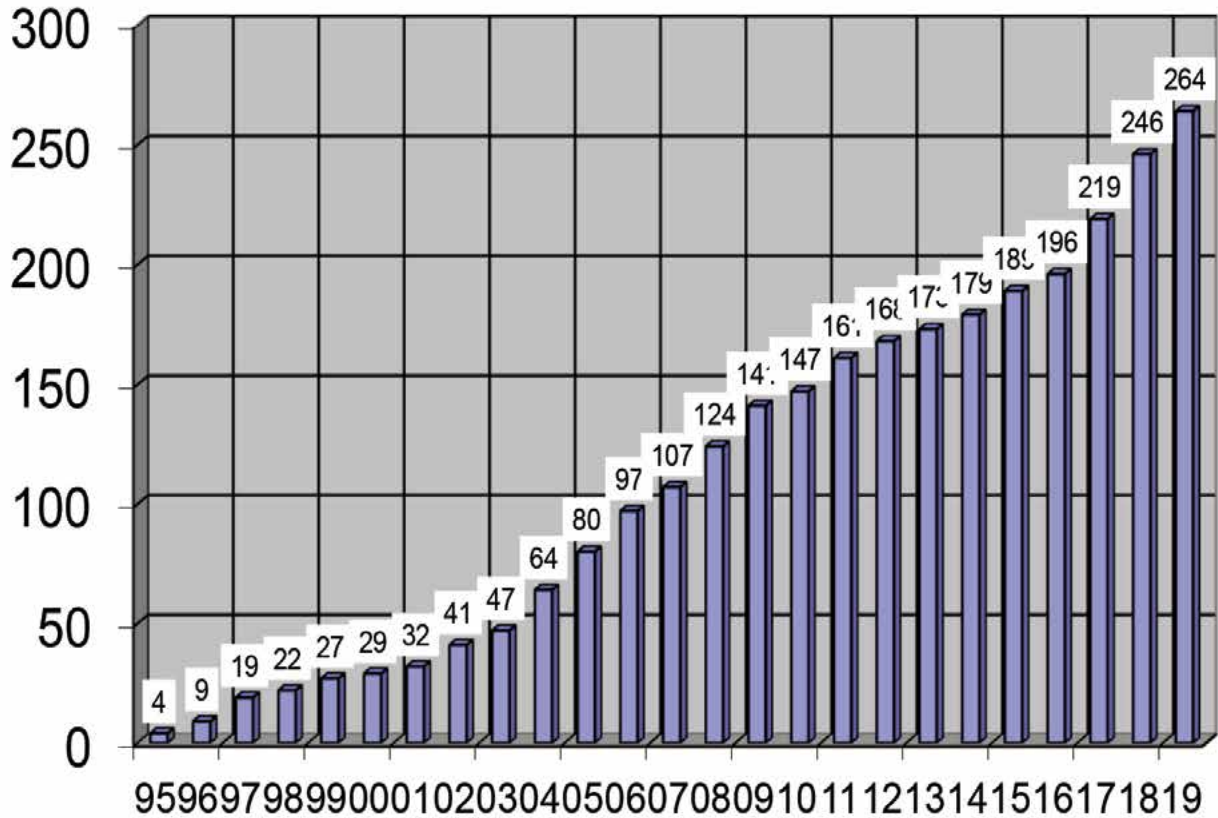
2019 Revenue distribution



organizations' accreditation or recognition
Trainings
Interest
Development funding from state budget **On**
going funding from state budget

The growth in number of accredited laboratories

Labs numbers over ISRAC's years



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.