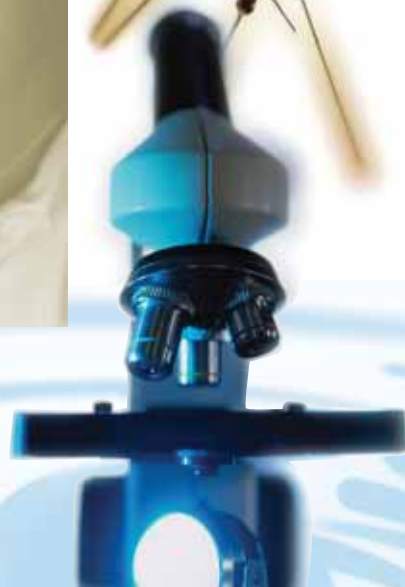




Ministry of Industry, Trade & Labor



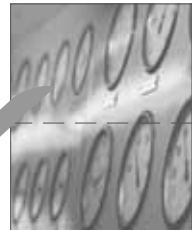
**ISIRAC**  
**Israel Laboratory Accreditation Authority**



# Annual Report

Year  
**2009**





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A few months ago I joined the Israeli Lab Accreditation Authority (ISRAC) as the representative of Israeli academia, and therefore, as Chairman, an opportunity that I regard as a privilege. On joining I was pleased to see how dedicated the people in the authority are, and I found an organization that struggles to adhere to the highest professional standards.

ISRAC was established about 13 years ago as a highly important national facility. There are hundreds of laboratories dispersed throughout the country, providing analytical services in medical, engineering, chemical, structural, and agricultural areas. Israel's health, security and economic strength depend on the reliability of these analytical services. In addition, the available analytical services are important both for Israeli society to have confidence in the quality of products that we produce here, and for our export products to be well accepted overseas. In our country, ISRAC is the only formal national tool available for maintaining the high standards of all the analytical laboratories, standards that are adopted by the most advanced countries throughout the world.

The Authority provides current accreditation to 141 laboratories in different testing areas. 15 employees operate the 335 assessors who, on a current basis, supervise all the laboratories under our umbrella and endeavor to ensure that the accreditation that we provide them has a sound basis. 2009 and the first months of 2010 can be considered as very successful and prolific for ISRAC. 17 new organizations were accredited and 18 workshops were organized for various organizations. In addition, employees of the Authority participated in 6 important international symposia, as Israel's relationship with parallel international organizations is extremely important. ISRAC has formal agreements with the International Laboratory Accreditation Cooperation (ILAC) and the European Accreditation (EA) organization. Within this framework, ISRAC is routinely evaluated by representatives from these organizations. A recent evaluation took place in March 2010. We received very positive feedback regarding our level of operation and management system, and were advised that the Authority conforms to the standards of ISO/IEC 17011. Some additional highly constructive comments that we received from the evaluation will help us to further improve our services.

I should also acknowledge with great satisfaction the excellent relationship that we have with all the formal Israeli governmental bodies with whom we work, including the Ministries of Finance, Agriculture, Industry and Commerce, and Law.

Over the years ISRAC has demonstrated a very balanced and responsible operation from the financial point of view. The annual reports always reflected a balanced and reasonable budget. Consequently, we benefit from the cooperation and full confidence of all the governmental bodies with whom we work.

At present ISRAC is in the process of nominating a new manager (CEO). We have received many applications from excellent people, which means that ISRAC is highly appreciated as an important and challenging working place. I feel sure that we will be able to have a new CEO who will successfully lead ISRAC. It should also be mentioned that presently some re-organization is taking place in among ISRAC's Board of Directors, with those members who have concluded their long-term service will be replaced by new members. Hence, ISRAC continues to demonstrate itself as a dynamic organization. This letter is written only a few days before Israel's 62nd Day of Independence. Our true independence definitely depends on the efficiency and high standards of operation of bodies such as ISRAC. I look forward to ISRAC's continuing excellent and prolific contribution to our society. And now, in conclusion, I want to thank my colleagues at ISRAC for their dedication and devotion towards maintaining a high standard of work, and I wish you all everything of the best, good health, and happiness.

Sincerely yours,  
**Prof. Doron Aurbach**  
Chairman



**Improving ISRAC's services to interested parties**

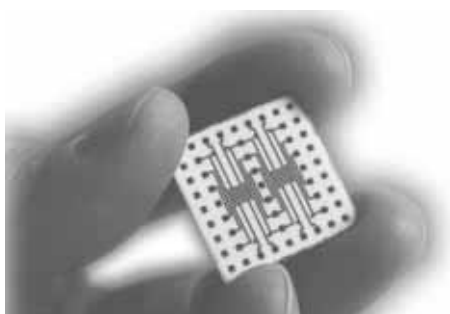
ISRAC was established by law on April 1997, in order to accredit laboratories to various activities. This accreditation contributes to effective transferring of goods and services in Israel and in foreign markets, while saving resources. The accreditation's advantage can be briefly described by the motto: "Tested Once Accepted Everywhere".

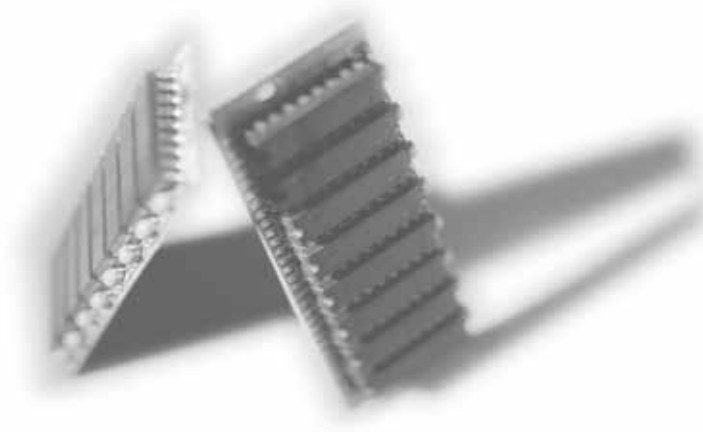
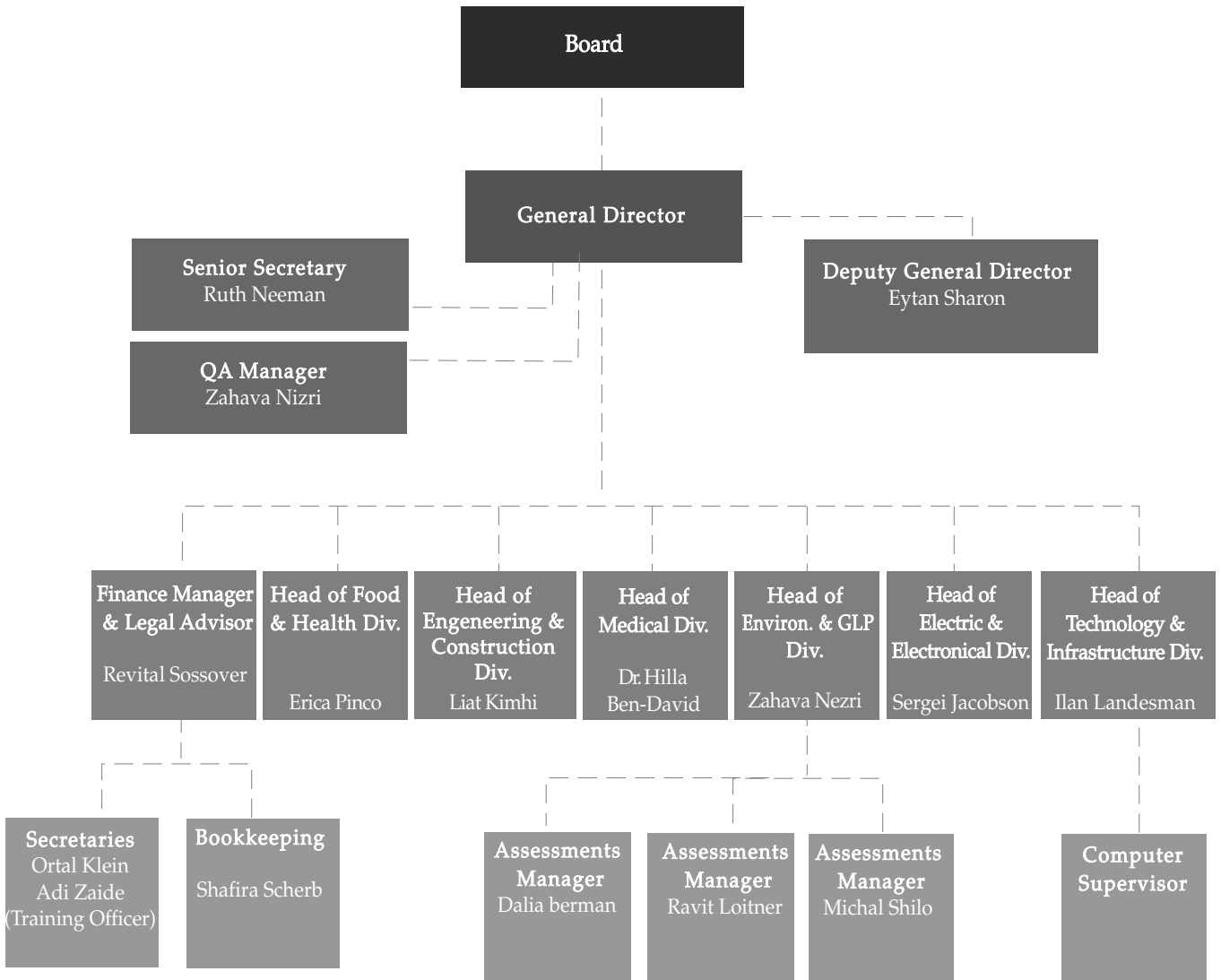
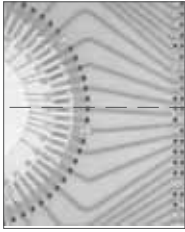
To implement this motto at ISRAC means to allow maximum accessibility to information about accredited laboratories and their scope, for all decision makers and other interested parties.

ISRAC had accredited about 150 organizations, most of them with many accredited activities. Although detailed information appears on ISRAC's website, it is not always user friendly. In order to improve the form of the information available for public use, in 2009 ISRAC has began a project of creating a computerized infrastructure, including a search engine on its website. This project, as well as updating the website, is planned to come into completion at the end of 2010.

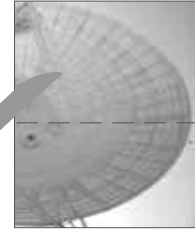
I believe that accessibility to information and ease of locating relevant data, will contribute to greater demand for accreditations services provided by ISRAC, and to a greater confidence of users, including regulators, in these accreditations.

Sincerely yours,  
**Eytan Sharon**  
Deputy General Manager





## About ISRAC and ways of establishing contractual relations



The early 1990s 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 blocs. The most important of which are EA - European Union countries, and APLAC - the Asian and Pacific countries. Each bloc sets 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 acts 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 in the Ministry of Industry and Trade 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 this, the minister decided in 1993 to establish the Israel Laboratory Accreditation Authority (ISRAC); an advisory committee was established and charged with developing the necessary infrastructure for ISRAC's activities and with initiating the process of accrediting laboratories. In 1995 the committee began to accredit laboratories. The committee's work led, in April 1997, to legislate the Israel Laboratory Accreditation Authority Law, 1997 (hereinafter "the Law"). Among other aspects, the Law defines the following functions and authorities for ISRAC:

- To determine, with the minister's authorization, the areas of accreditation in which it is active.
- To define requirements for the accreditation of measurement, calibration and test laboratories.
- To ensure that laboratories meet the requirements for accreditation and, accordingly, to continue or withdraw the accreditation of laboratories.
- To serve as the exclusive representative of the state in all matters relating to mutual recognition of the accreditation systems of other countries or of international organizations.
- To initiate supplementary activities to the accreditation of laboratories, such as training, publicity and information.

### What is the Accreditation of a Laboratory?

The accreditation of a laboratory implies official recognition of that laboratory's professional capability and competence to perform specific types of tests, measurements and calibrations. Accreditation is





available for all types of calibration and test laboratories, whether these are part of a factory, or belong to the public or 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 laboratory to evaluate whether it is performing its work properly and in accordance with international standards.

Important! Accreditation of a laboratory provides formal recognition of its professional capability, thus constituting a means for enabling clients and major consumers in the economy, such as the enforcement authorities, to assure that they receive a reliable and qualitative service for tests, measurements 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 Guide 58 (1993): "Calibration and testing laboratory accreditation systems - General requirements for operation recognition".

During the year 2001 ISRAC was recognised 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 64 countries that have already signed MRAs for any test or calibration performed by a laboratory accredited by ISRAC.

ISRAC's employees play an active role in ILAC's professional committees. In addition, the General Director of ISRAC is a member of the Executive Committee of ILAC.

### 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 a MRA with the European Union and a Memorandum of Understanding (MoU) with the EPA. This MoU will become an MRA following a visit of a delegation from the EPA to the recognized laboratories and to ISRAC's offices. At the end of last year ISRAC was invited as an observer to a committee discussing these issues at the OECD.

Israeli research facilities interested in participating in pre-clinical experiments in the fields of pharmaceuticals, cosmetics, pesticides, food additives and environmental toxicity are required to receive recognition that they operate in accordance to the directives of the OECD, EPA or FDA. As of the end of 2009 eleven research facilities have been recognized for GLP.

## ISRAC's Commitments

The entire staff of ISRAC, including its managers, assessors and consultants, sign a confidentiality agreement to protect the confidentiality of information belonging to 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

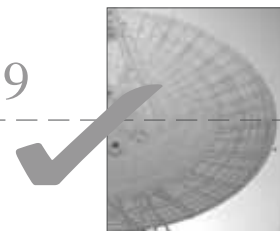
Laboratory accreditation may be provided for any type of properly documented test, measurement or calibration. At present, ISRAC accredits for the following types of tests / calibrations:

### Types of tests

- Destructive tests
  - Chemical
  - Physical
  - Biological / microbiological
- Non-destructive tests

### Types of calibrations

- Mechanical sizes
- Electrical sizes
- Optical sizes
- Physical sizes



Accreditation is provided in the following fields:

- Construction
- Paving and soil
- Food and Water
- Cosmetics
- Fuel and bitumens
- Calibration
- Non-destructive tests (NDT)
- Information Technology
- Metals and Semi-metals
- Environment
- Electricity
- Alcoholic beverages
- Health (Medical laboratories, Forensic and Medical research)
- Lifting Devices
- Perssure vessels
- Animal Food
- Agriculture: Derection of damages plants

ISRAC is working to develop additional fields of accreditation, in order to meet the demands of the Israeli market and specific clients.

ISRAC is active in the recognition of laboratory facilities operating in accordance with the GLP directives of the FDA, EPA, and OECD. Recognition for GLP is provided in the following fields:

- Cosmetics
- Industrial chemicals
- Pharmaceuticals/medicinal products
- Food Additives
- Animal feed additives
- Pesticides

## Requirements for an Accreditation

ISRAC's criteria and rules for the accreditation of laboratories were based in 2005 on the international standard ISO/IEC 17025-1999: "General requirements for the competence for testing and calibration laboratories." Medical laboratories are accredited according to a specific standard, ISO 15189, which is based on the ISO/IEC 17025. In addition, specific criteria for various fields complete the general criteria. In practical terms, ISRAC ascertains the following in accrediting a laboratory:

- Laboratory facilities, professional capability and systems are appropriate for performing the tests and calibrations listed in the scope of accreditation.
- The quality system of the laboratory meets all requirments of the relevant standard ISO/IEC 17025 (1999) or ISO 15189 and thereby sections of ISO 9001 (1994), ISO 9002 (1994) - and is properly documented and fully implemented.
- The laboratory meets ISRAC's complementary criteria for the accreditation of laboratories in areas relating to its scope of accreditation, relating primarily to requirements in the Israeli law or reality, or constituting an extension or explanation of generalized statements in the standard.  
Accreditation for a laboratory is not generalized, but granted for specific methods of testing and calibration, as detailed on ISRAC's Internet site, [www.israc.gov.il](http://www.israc.gov.il).
- ISO/IEC 17025 standard was updated in 2005. In 2006 compliance to the new standards is mandatory.

## Our Recommendations to Laboratory Service Consumers

ISRAC recommends that those who use the results of measurements, tests or calibration ascertain which laboratories are accredited and what is their scope of accreditation. The scope of accreditation defines the specific types of test or calibration capabilities for which the laboratory has received accreditation.





## Annual Report 2009



### The Added Value for the Accredited Laboratory

An accredited laboratory is permitted to mention its accreditation on its documents and test certificates, relating to the tests for which it is accredited. Accreditation is performed in accordance with international rules recognized by members of ILAC in 64 countries, including Western European nations, United States, Japan, Australia, India, China and additional countries around the world.

The quality system provides a tool for ensuring that the laboratory will monitor its activities and draw conclusions in order to ensure constant improvement. Accreditation is recognized by the European governmental authorities and, in many cases, provides a basis for their recognition. Laboratories that function in accordance with the rules of accreditation improve the efficiency of work processes, including: proper first-time implementation, reducing the number of repeat testing; preventative maintenance of equipment, saving unnecessary investments in repairs and acquisitions, and so on.

#### How to Contact ISRAC:

Address for letters: Kineret St. Airport City, P.O. Box 89 Lod Airport 70150

Phone: 03-9702413, Fax: 03-9702413, E-mail: [israc@israc.gov.il](mailto:israc@israc.gov.il), Web Site: [www.israc.gov.il](http://www.israc.gov.il)

Job Description	Name	Degree	Phone Number	E-mail
General Director				
Deputy General Director	Eytan Sharon	M.Sc, C.Q.E	03-9702727(219)	<a href="mailto:eytans@israc.gov.il">eytans@israc.gov.il</a>
Head of Electric & Electronical Div.	Sergei Jacobson	M.Sc.	03-9702727(205)	<a href="mailto:sergeij@israc.gov.il">sergeij@israc.gov.il</a>
Head of Technology & Infrastructure Div.	Ilan Landesman	B.A C.Q.E	03-9702727(202)	<a href="mailto:ilanl@israc.gov.il">ilanl@israc.gov.il</a>
Head of Engineering & Construction Div.	Liat Kimhi	B.Sc. Eng.	03-9702727(204)	<a href="mailto:liatk@israc.gov.il">liatk@israc.gov.il</a>
Head of Food & Health Div.	Erica Pinco	M.Sc.	03-9702727(208)	<a href="mailto:erica@israc.gov.il">erica@israc.gov.il</a>
Finance Manager & Legal Advisor	Revital Sossover	Advocate תורנית B.A	03-9702727(209)	<a href="mailto:revitals@israc.gov.il">revitals@israc.gov.il</a>
Head of Quality, Environmental & GLP Div.	Zahava Nezri	B.Sc	03-9702727(203)	<a href="mailto:zahavan@israc.gov.il">zahavan@israc.gov.il</a>
Head of Medical Div.	Hilla Ben-David	Ph.D	03-9702727(212)	<a href="mailto:hilab@israc.gov.il">hilab@israc.gov.il</a>
Assessment Manager	Michal Shilo	B.Sc	03-9702727(201)	<a href="mailto:michals@israc.gov.il">michals@israc.gov.il</a>
Assessment Manager	Dalia Berman	Ph.D	03-9702727(226)	<a href="mailto:daliab@israc.gov.il">daliab@israc.gov.il</a>
Assessment Manager	Ravit Loitner	B.Sc	03-9702727(228)	<a href="mailto:ravitl@israc.gov.il">ravitl@israc.gov.il</a>
Senior Secretary	Ruth Neeman		03-9702727	<a href="mailto:ruthien@israc.gov.il">ruthien@israc.gov.il</a>
Secretary	Ortal Klein		03-9702727(200)	<a href="mailto:ortals@israc.gov.il">ortals@israc.gov.il</a>
Secretary	Adi Zaide	B.Ed	03-9702727(207)	<a href="mailto:adiz@israc.gov.il">adiz@israc.gov.il</a>
Book keeping	Shafira Scherb		03-9702727(209)	<a href="mailto:shafiras@israc.gov.il">shafiras@israc.gov.il</a>



Last year we set ourselves the following goals:

- Approval of the revised law
- Enhancing the relations with all government regulators
- Cooperation with international accreditation and standard organizations
- Increasing the number of accredited laboratories and the technologies they are accredited to.
- Enhancing the cooperation with the Industry Association, Consumer laboratories, Export Institution and Chamber of Commerce.
- Success in EA assessment

The goals that were completely under our control have been fully achieved. Regrettably, we did not reach this success concerning other goals that were depended on cooperation with others.

### Approval of the revision in ISRAC's law

This is an ongoing mission. The political situation did not enable the approval of the revised edition of the law. The legal department in the Ministry of Industry Commerce and Employment had issued a detailed document pointing out the need of the state in more tools and means to enhance the enforcement. Following this document there were many meetings between our legal department and the legal departments of the Ministry of Industry Trade and Commerce and the Ministry of Legal Affairs. The revision of ISRAC's law will facilitate, among other things, the implementation of the new regulations in the construction field.

### Emphasizing the Issue of test methods validation

Test methods validation is a detailed requirement of the standard to laboratories competence. ISRAC had issued a policy procedure on this matter. In 2009, validation of test methods was one of the main issues at the surveillance and reassessment visits at the laboratories. Test methods validation assures the laboratories as well as their customers that the methods used by the laboratory are indeed suitable to their intended use. The validation process raises problems that their solutions contribute to improvement of the accuracy and the reliability of the test results.

### Accreditation of new laboratories

17 new laboratories were accredited in 2009. The total number of accredited organisation at the end of 2009 has reached 141 compared to 116 at the end of 2008. No significant breakthrough in the number of accredited medical laboratories happened in spite of the fact that this area has a great potential.

### Cooperation with international accreditation and standardization organizations

ISRAC has active representatives in the following organization:

- EA – European Accreditation
- ILAC – International Laboratory Accreditation Cooperation
- OECD – Organization for Economic co-operation and Development in The GLP (Good Laboratory Practice) area.

### The world financial crisis

ISRAC was not affected by the economic crisis in 2009.



Governmental office	Laboratory services	Requires accreditation	Ministerial laboratories are accredited
Ministry of Health	Water and food Clinical labs	✓ -	✓ ✓ (partial)
Ministry of Agriculture	Pesticides, Remnants of pesticides (required for export)	- ✓	✓ ✓
Ministry of Defense	All fields	✓	No labs
Ministry of Trade, Labor & Industry	Commissioner of standards Radiation	✓ -	No labs No labs
Ministry of Trade, Labor & Industry	Industrial hygiene Noise	✓ ✓	✓ ✓
Ministry of Environmental Protection	Radiation Soil, wastewater, fuels Air Quality Pesticides	In process ✓ ✓ In process	No labs No labs No labs No labs
Ministry of Internal Affairs	Population of buildings (form 4) Construction	✓ ✓	No labs No labs
Infrastructure	Fuel Water meters Electricity testing Water Quality	✓ ✓ - -	No labs No labs - ✓
Transportation	Vehicles Traffic control devices	- ✓	No labs No labs
Ministry of Housing and Construction	Construction	✓	No labs
Ministry of Homeland Security	Forensic Science	-	✓



►►► The main activities planned for the year 2010

- Approval of the new ISRAC law.
- Broadening the cooperation between ISRAC and all regulators.
- Cooperation with international accreditation and standardization organizations.
- Enhancing the awareness for uncertainties in measurements with special emphasis on uncertainty in sampling.
- Increasing the number of accredited organizations and technologies they are accredited to.
- Broadening the cooperation with the consumer organizations, the Manufacturers Association of Israel, the export institute and the chambers of commerce.
- Organizing professional courses to quality issues concerning labs.
- Upgrading ISRAC's computer system.
- Upgrading ISRAC's website.
- Organizing the EA assessment of ISRAC, and implementing their remarks and comments if given. Passing the assessment is an essential condition for mutual recognition between ISRAC, EA and ILAC.
- Developing new areas of accreditation and new testing method in existing areas.



# Annual Report 2009

## Budget for 2009 and 2010

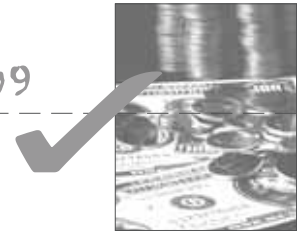


### Budget for 2009 and 2010

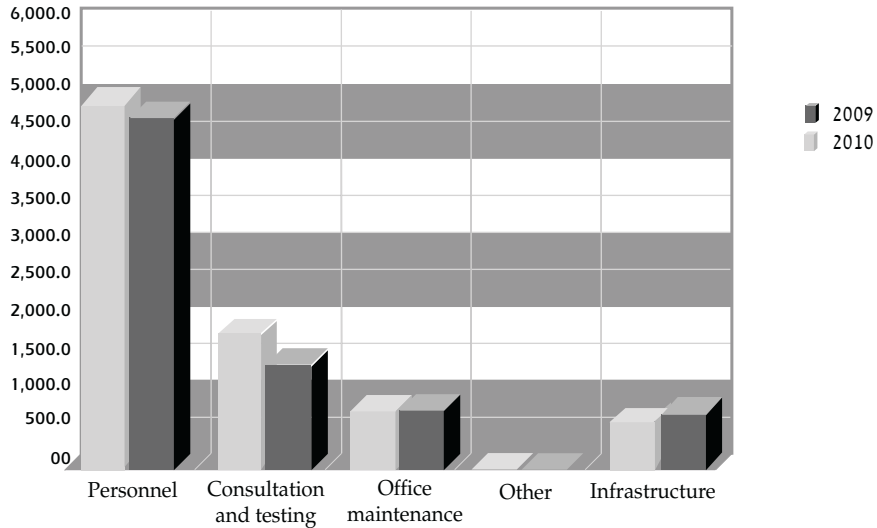
	2009 budget	2010 budget	Nominal Change
	NIS 000's	NIS 000's	%
<b>Expenditure</b>			
Regular operations	4,640.9	5,210.8	12.3
Development	3,454.9	3,388.7	-1.9
<b>Total Expenditure</b>	<b>8,095.8</b>	<b>8,599.5</b>	<b>6.2</b>
<b>Income from Operations</b>			
Accreditation and surveillance	3,498.0	3,912.7	11.9
Training and GLP inspections	200.0	200.0	0.0
<b>Total Income from Operations</b>	<b>3,698.0</b>	<b>4,112.7</b>	<b>11.2</b>
<b>Income from Funding</b>			
Funding of development - State budget	3,527.0	3,500.0	-0.8
Regular funding - State budget	0.0	0.0	0.0
Preceding Year's Surplus	845.8	886.8	4.8
Income from interest	25.0	100.0	
<b>Total Income from Funding</b>	<b>4,397.8</b>	<b>4,486.8</b>	<b>2.0</b>
<b>Total Income</b>	<b>8,095.8</b>	<b>8,599.5</b>	<b>6.2</b>

### Expenditure

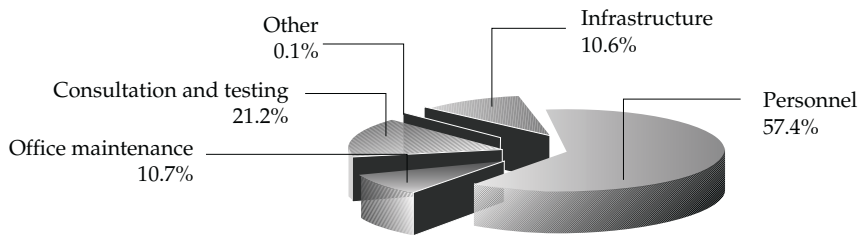
		2009 budget	2010 budget	Nominal Change
		NIS 000's	NIS 000's	%
<b>Expenditure</b>				
1.0	Personnel	4,831.0	4,937.4	2.2
2.0	Consultation and testing	1,401.7	1,824.6	30.2
3.0	Office maintenance	909.3	921.5	1.3
4.0	Other	8.0	8.0	0.0
	<b>Total operating expenditure</b>	<b>7,150.0</b>	<b>7,691.5</b>	<b>7.6</b>
	Development element	-2,517.1	-2,492.7	-1.0
	<b>Total regular operations</b>	<b>4,632.9</b>	<b>5,198.8</b>	<b>12.2</b>
5.0	Infrastructure	945.8	908.0	-4.0
	Development components	2,517.1	2,492.7	-1.0
	<b>Total development</b>	<b>3,462.9</b>	<b>3,400.7</b>	<b>-1.8</b>
	<b>Total</b>	<b>8,095.8</b>	<b>8,599.5</b>	<b>6.2</b>



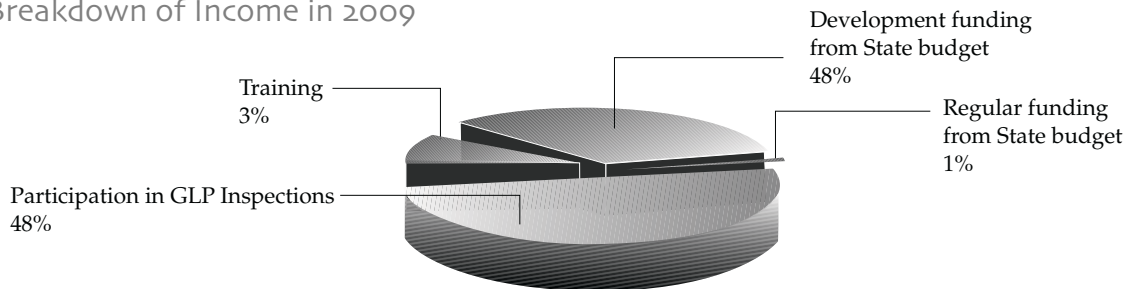
Forecast of Expenditure in the 2010 Budget in Comparison with the 2009 Budget:



Breakdown of Expenditure in 2009



Breakdown of Income in 2009



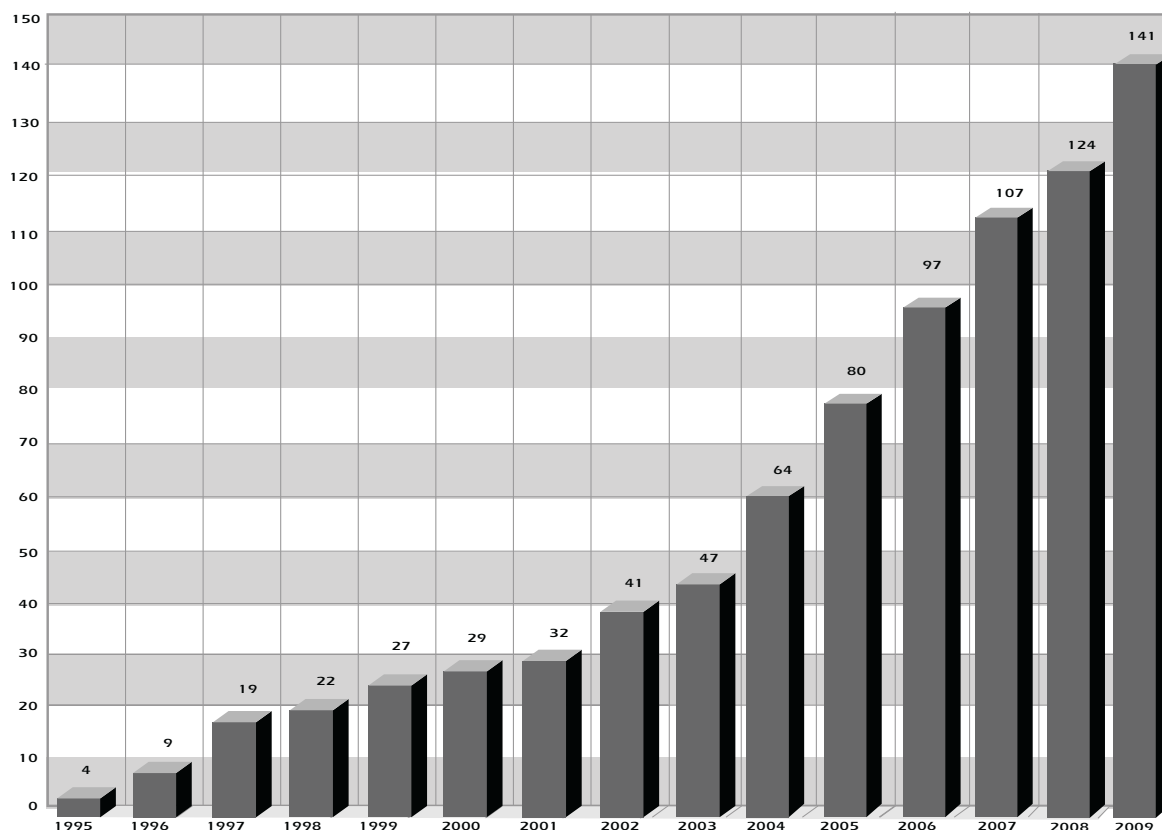
As of January 2010, 130 laboratories have received accreditation, and 11 research facilities received recognition to GLP. 26 laboratories are in the process of accreditation.

Department	No. of accredited labs.	No. of labs. in the process of accreditation
Engeneering	18	3
Health	24	0
Environment	19	1
Medical	14	0
Electric & Electronics	22	13
Infrastructure	33	8
GLP (accreditation)	11	1





The following chart shows the growth in the number of accredited laboratories according to ISRAC's years of operation (including the advisory committee that preceded ISRAC)



Information about the accreditation process is available to the laboratories at the ISRAC website ([www.israc.gov.il](http://www.israc.gov.il)).

## Freedom of information and transparency in ISRAC

ISRAC is a national public organization established by law. As such, ISRAC operates in accordance with Israel's Freedom of Information Law. ISRAC makes every effort to publicize and open its activities for the public, including clients, regulators, interested bodies and others.

In accordance with the law, ISRAC publishes its activities through its annual report.

ISRAC's quality manual (for accreditation and GLP) and some of its policies are available on ISRAC's Web site - [www.israc.gov.il](http://www.israc.gov.il). This site also provides the list of laboratories accredited by ISRAC, including their scope of accreditation, as well as ISRAC guidelines and extensive additional information. ISRAC's web site is bilingual (Hebrew & English).

Every four months, ISRAC publishes a newsletter, "Reshuton", providing news about ISRAC and accreditation, abstracts of some of the procedures, obligatory requirements, professional articles, information about training and seminars, updated lists of accredited laboratories and their scope of accreditation, etc. The "Reshuton" is distributed to about 2,000 readers, and is also available to participants in seminars and, upon request, to any interested parties. The "Reshuton" is also published on the Web site.

ISRAC maintains ongoing dialogue with its clients through meetings, courses and feedback questionnaires. ISRAC publishes information about itself and the accreditation process, which is available free of charge and on demand. This booklet provides general explanations about ISRAC's work and operations and details on the accreditation process.

In addition to the above, the administrative guidelines binding ISRAC, as well as other information (subject to ISRAC's confidentiality restrictions), may be read by any citizen at the ISRAC offices daily between 8:30 AM - 5 PM, by prior arrangement.