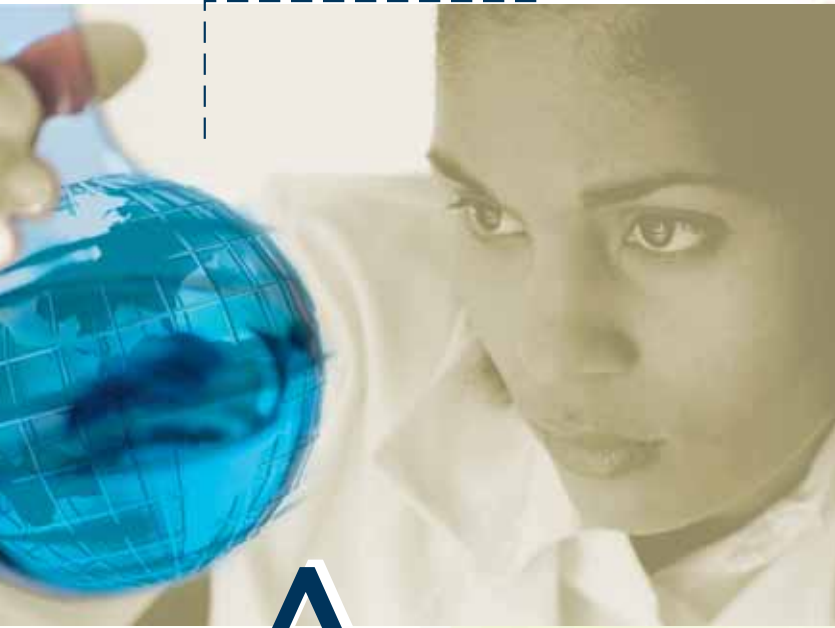




Ministry of Industry, Trade & Labor



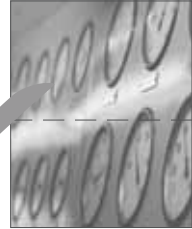
ISRAC
Israel Laboratory Accreditation Authority



Annual Report

Year
2010





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ISRAC was established about 14 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.

After a very serious and rigorous formal searching process, Mrs. Etty Feller was nominated as the general director (CEO) of ISRAC. The search committee which I chaired, examined several dozen very good candidates who very much wanted the position. This searching process demonstrated very clearly that ISRAC is a very prestigious and challenging working place. Mrs. Feller brings with her important professional experience, diligence a very good management capability and strong ambition to advance ISRAC in all important directions: the professional one, the scope and depth of work and the social aspects as well as maintaining excellent relationships and good spirit among the staff of ISRAC.

The Authority provides current accreditation to 147 laboratories in different testing areas. 15 employees operate the 106 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.

2010 can be considered as a very successful and prolific year for ISRAC. 6 new organizations were accredited and 10 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 to ISRAC and to Israel.

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. It is important to note that in order to fully adjust ourselves to the standards of the OECD countries (to which we belong) and especially the standards of the European Commission, ISRAC has to undergo revolutionary changes in the volume of work, towards the end of 2011. I want to express my highest appreciation to the excellent preparation work that was carried out by the senior staff of ISRAC during recent months, in order to meet these challenges. Due to their work, I think that we are well prepared.

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.

It should also be mentioned that presently some re-organization is taking place in among ISRAC's Board of Directors, where 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 several weeks before our national holiday of independence, namely, Chag Pessach. The parameters that ensure our independence include hard work at high standards of reliability and honesty. ISRAC can definitely be considered as a body that works at high standards. I look forward to ISRAC's continuing excellent and prolific contribution to our society.

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

At the center of the year 2010 was the international assessment which was conducted at ISRAC and which included all the accessible accreditations. The assessment was conducted by a delegation of the EA (European Accreditation):

Lal Ian- UKAS, United Kingdom, Team Leader, Inspection

Anna Stefanidou ESYD, Greece, Team Member, Testing

Andreas Odin DAKKS, Germany, Team Member, Calibration

This re-evaluation is a requirement of the EA in order to maintain the existing bilateral agreement between the Israel Laboratory Accreditation Authority, and all states/organizations who are members of the EA in the testing , calibration and inspection bodies. ISRAC passed the international assessment successfully.

The main finding of the assessment was the requirement to change the surveillance assessments policy and ensuring its implementation. Based on this finding, ISRAC carried out extensive work from which the benefits shall be published in the coming year. Implementation of the change is obligated by the EA no later than January 2012.

Later in the year, after the completion of the assessment, ISRAC staff invested much effort in to the promotion and dialogue of the ISRAC law. Meetings were held with the Government Ministries and we hope that in the coming year we shall be able to complete the task. ISRAC employees believe that their activities contribute substantially to both the professional and normative levels of the activity of the accredited organizations.

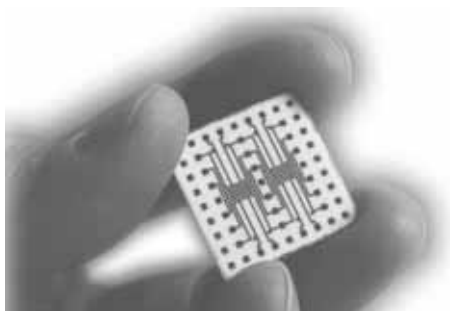
This year too, the staff of ISRAC braced the cooperation of various regulators. This collaboration provides the regulators with a tool for monitoring the developments in their fields without putting a burden on their ongoing activities and annual budget.

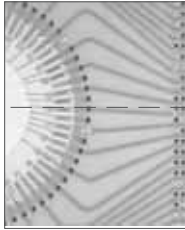
Simultaneously, training activities were conducted for the employees of accredited bodies, technical assessors, interested parties and consumers in order to raise awareness to the issue of measurement and the professionalism of executing the measurements which constitute the basis for formulating decisions and consolidation of policy.

I wish to thank the employees of ISRAC, a heartfelt thank you for the effort and willingness to work tirelessly in the various fields of activity of ISRAC, in promoting the mission of ISRAC "promoting quality and professional competence of calibration bodies/assessing in harmony with the world for the state and its citizens".

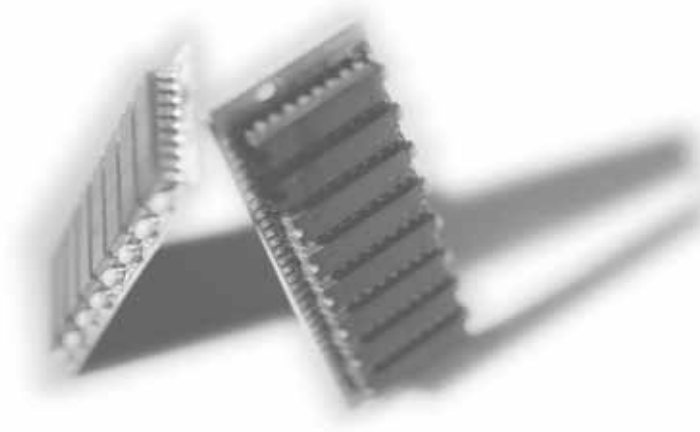
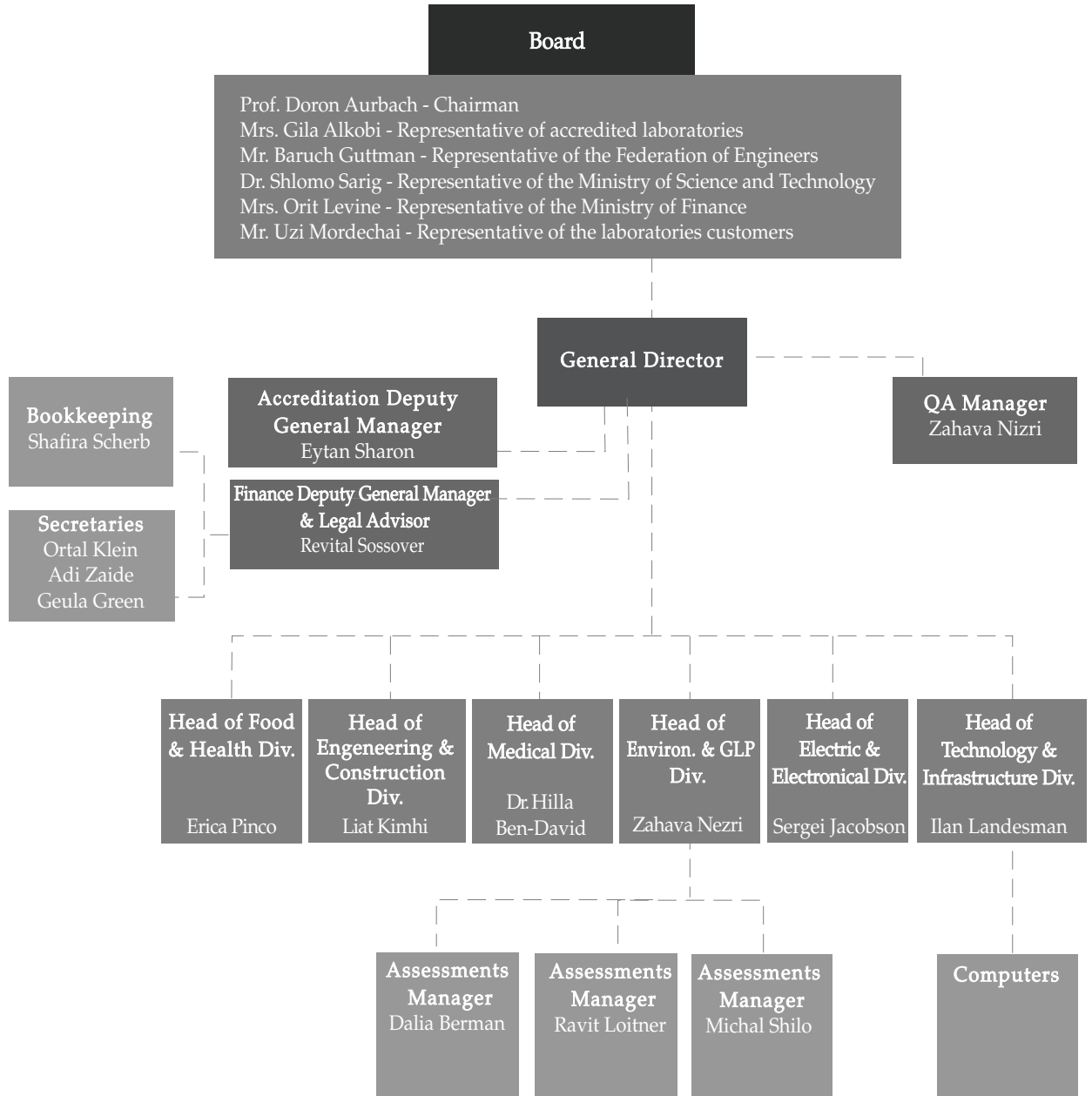
To the various regulators involved with promoting the ISRAC law, to the interested parties and to our public consumers who put their trust in the activities of ISRAC, thank you.

Etty Feller
General Manager

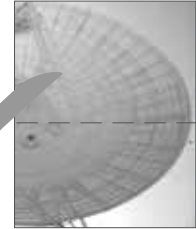




Organization chart



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 blocks. The most important of which are EA - European Union countries, and APLAC - the Asian and Pacific countries. Each block 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 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 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.

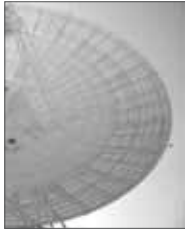
In 1992, in preparation for the establishment of an accreditation system in Israel, meeting international standards and gaining international recognition, the Minister of Industry and Trade appointed a committee to examine the issue of the accreditation of laboratories.

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 an 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

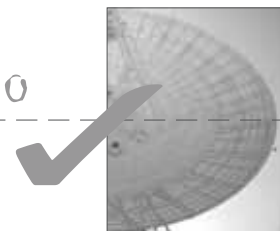
Laboratory accreditation may be provided for any type of properly documented test, measurement or calibration. At present, ISRAC accredits for the following types of tests / calibrations:

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
- Pressure vessels
- Animal Food
- Agriculture: Detection of damage to plants
- Medical Devices

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 food additives
- Pesticides

Requirements of Accredited Laboratories

ISRAC's criteria and rules for the accreditation of laboratories in 2005 were based 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 requirements 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.
- 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 their scope of accreditation. The scope of accreditation defines the specific types of test or calibration capabilities for which the laboratory has received accreditation.



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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, Web Site: www.israc.gov.il

Job Description	Name	Degree	Phone Number	E-mail
General Director	Etty Feller		03-9702727(208)	ettyf@israc.gov.il
Deputy General Director	Eytan Sharon	M.Sc, C.Q.E	03-9702727(219)	eytans@israc.gov.il
Finance Deputy General Manager & Legal Advisor	Revital Sossover	ECO, B.A., L.L.B	03-9702727(206)	revitals@israc.gov.il
Head of Electric & Electronical Div.	Sergei Jacobson	M.Sc.	03-9702727(205)	sergeij@israc.gov.il
Head of Technology & Infrastructure Div.	Ilan Landesman	B.A C.Q.E	03-9702727(202)	ilanl@israc.gov.il
Head of Engineering & Construction Div.	Liat Kimhi	B.Sc. Eng.	03-9702727(204)	liatk@israc.gov.il
Head of Food & Health Div.	Erica Pinco	M.Sc.	03-9702727(208)	erica@israc.gov.il
Head of Quality, Environmental & GLP Div.	Zahava Nezri	B.Sc	03-9702727(203)	zahavan@israc.gov.il
Head of Medical Div.	Hilla Ben-David	Ph.D	03-9702727(212)	hilab@israc.gov.il
Assessment Manager	Dalia Berman	Ph.D	03-9702727(226)	daliab@israc.gov.il
Assessment Manager	Ravit Loitner	B.Sc	03-9702727(228)	ravitl@israc.gov.il
Secretary	Geula Green		03-9702727(213)	geula@israc.gov.il
Secretary	Ortal Klein		03-9702727(200)	ortals@israc.gov.il
Secretary	Adi Zaide	B.Ed	03-9702727(207)	adiz@israc.gov.il
Bookkeeping	Shafira Scherb		03-9702727(209)	shafiras@israc.gov.il



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 dependent on cooperation with others.

Approval of the revision of ISRAC's law

This is an ongoing mission.

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. A draft was decided upon which will, seemingly, be distributed in the first half of the year 2011 for comments from the Government Ministries.

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 2010, 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. The validation process of all test methods in all the laboratories was completed after great effort, with only a few exceptions.

Accreditation of new laboratories

9 new laboratories were accredited in 2010 (based on management review figures).

The total number of accredited organizations at the end of 2010 reached 147, compared to 141 at the end of 2009.

No significant breakthrough in the number of accredited medical laboratories happened in spite of the fact that this area has 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 2010.



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 Traffic Police	- Beginning the process	✓ No labs



▶▶▶ The main activities planned for the year 2011

- Approval of ISRAC law (1997).
- Increasing the number of accredited organizations and increasing the scope of accreditation of the existing accredited organizations.
- Organizing professional courses to improve quality and professionalism in accredited organizations
- Developing new areas of accreditation and new testing methods in existing areas
- Upgrading ISRAC's computer system
- Upgrading ISRAC's website
- Implementing the change in the surveillance assessments policy of accredited organizations as a part of the mutual recognition requirements between ISRAC and EA and ILAC
- Broadening the cooperation between ISRAC and regulators in all Government Ministries, Manufacturers Association, Consumer Organizations, the Israel Export Institute, the Standards Institution of Israel and the Chambers of Commerce
- Cooperation with international accreditation and standardization organizations



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Budget for 2009 and 2011



Budget for 2010 and 2011

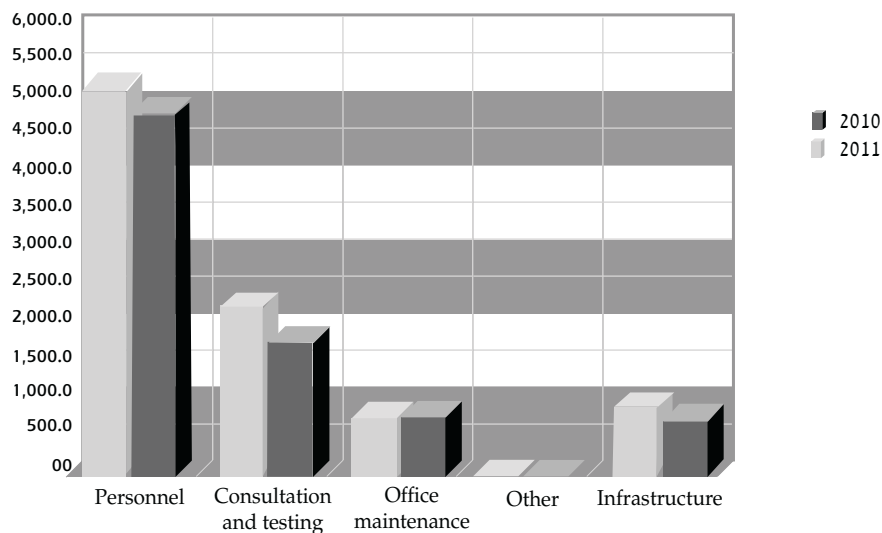
	2010 budget	2011 budget	Nominal Change
	NIS 000's	NIS 000's	%
Expenditure			
Regular operations	5,210.8	5,886.0	13.0
Development	3,388.7	3,711.2	9.5
Total Expenditure	8,599.5	9,597.2	11.6
Income from Operations			
Accreditation and surveillance	3,912.7	4,584.0	17.2
Training and GLP inspections	200.0	200.0	0.0
Total Income from Operations	4,112.7	4,784.0	16.3
Income from Funding			
Funding of development - State budget	3,500.0	3,500.0	0.0
Regular funding - State budget	0.0	0.0	0.0
Preceding Year's Surplus	886.8	1,113.2	25.5
Income from interest	100.0	200.0	100
Total Income from Funding	4,486.8	4,813.2	7.3
Total Income	8,599.5	9,597.2	11.6

Expenditure

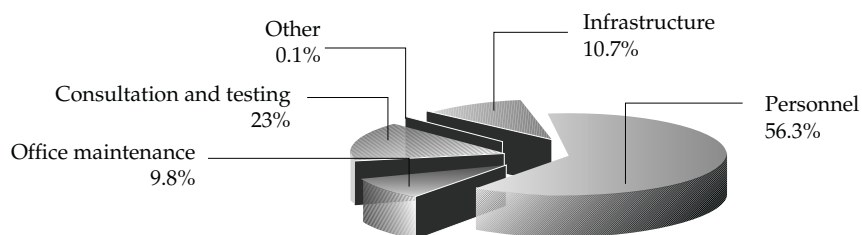
		2010 budget	2011 budget	Nominal Change
		NIS 000's	NIS 000's	%
Expenditure				
1.0	Personnel	4,937.4	5,407.7	9.5
2.0	Consultation and testing	1,824.6	2,211.2	21.2
3.0	Office maintenance	921.5	939.8	2.0
4.0	Other	8.0	10.0	25.0
	Total operating expenditure	7,691.5	8,568.7	11.4
	Development element	-2,492.7	-2,694.7	8.1
	Total regular operations	5,198.8	5,874.0	13.0
5.0	Infrastructure	908.0	1,028.5	13.3
	Development components	2,492.7	2,694.7	8.1
	Total development	3,400.7	3,723.2	9.5
	Total	8,599.5	9,597.2	11.6



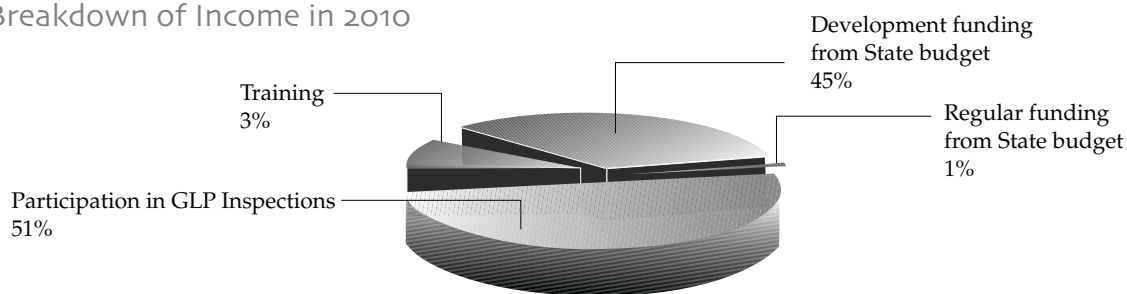
Forecast of Expenditure in the 2011 Budget in Comparison with the 2010 Budget:



Breakdown of Expenditure in 2010



Breakdown of Income in 2010

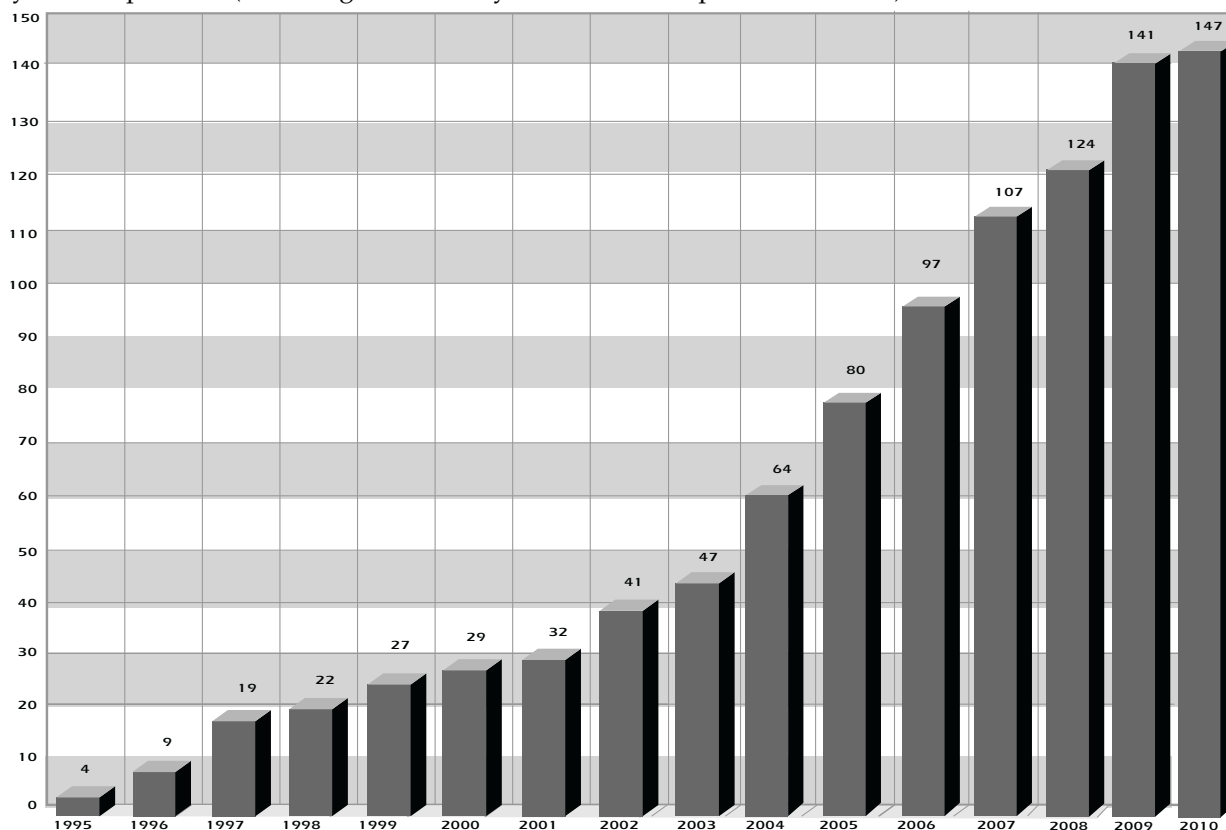


As of January 2011, 134 laboratories have received accreditation, and 13 research facilities received recognition to GLP. 23 laboratories are in the process of accreditation.

Department	No. of accredited labs.	No. of labs. in the process of accreditation
Engeneering	19	2
Health	27	1
Environment	18	2
Medical	12	3
Electric & Electronics	24	7
Infrastructure	34	7
GLP (accreditation)	13	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).

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. 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.