



Ministry of Industry, Trade & Labor



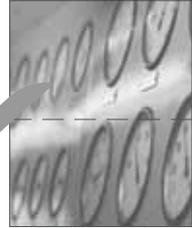
**ISRAC**  
Israel Laboratory Accreditation Authority



# Annual Report

Year  
2007





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**A**ccreditation of a laboratory is a proof of its capability and its technical competence to issue reliable and valuable test results for the client.

In the year 2007 ISRAC have began to accredit laboratories dealing with health and safety.

Those laboratories test air, radiation and noise in the worker's environment.

In the year 2007 ISRAC launched for the first time a 15 days course to lab quality managers. The course schedule included also a written final exam.

This course gave professional quality assurance tools to laboratory personnel that came to the quality area from some specific area.

An added value to the participants, in addition to the knowledge gained in the quality area, was improvement in the communication between accredited laboratories and ISRAC.

The course also gave practical tools to laboratories that are in the process of building their quality systems.

The main and ongoing task of ISRAC is to make the decision makers be aware that laboratories accreditation contributes considerably to the data that the decisions are based on.

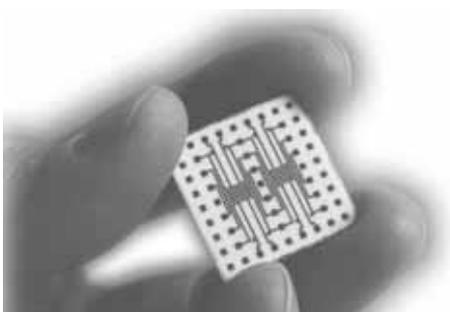
At the year 2008 ISRAC shall continue this awareness issue focusing on the medical sector.

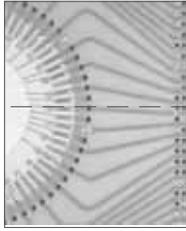
This sector contains half of the laboratories in the western civilization including Israel. Considerable part of the medical treatment instructions is based on laboratory's data.

Another challenge in 2008 is the preparation to the 4-year reassessment on ISRAC that is scheduled to the end of 2008 or the beginning of 2009.

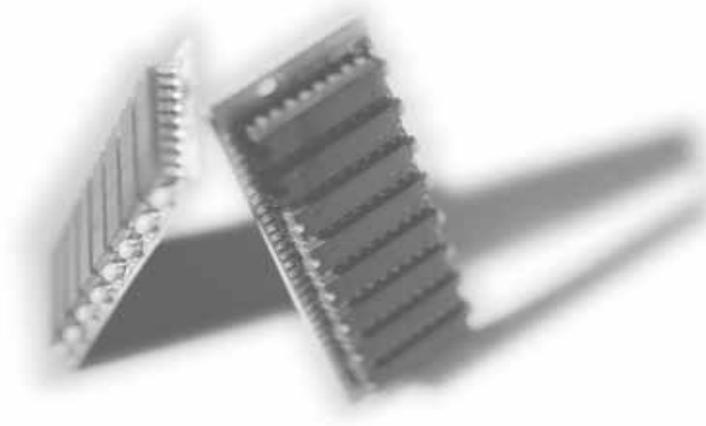
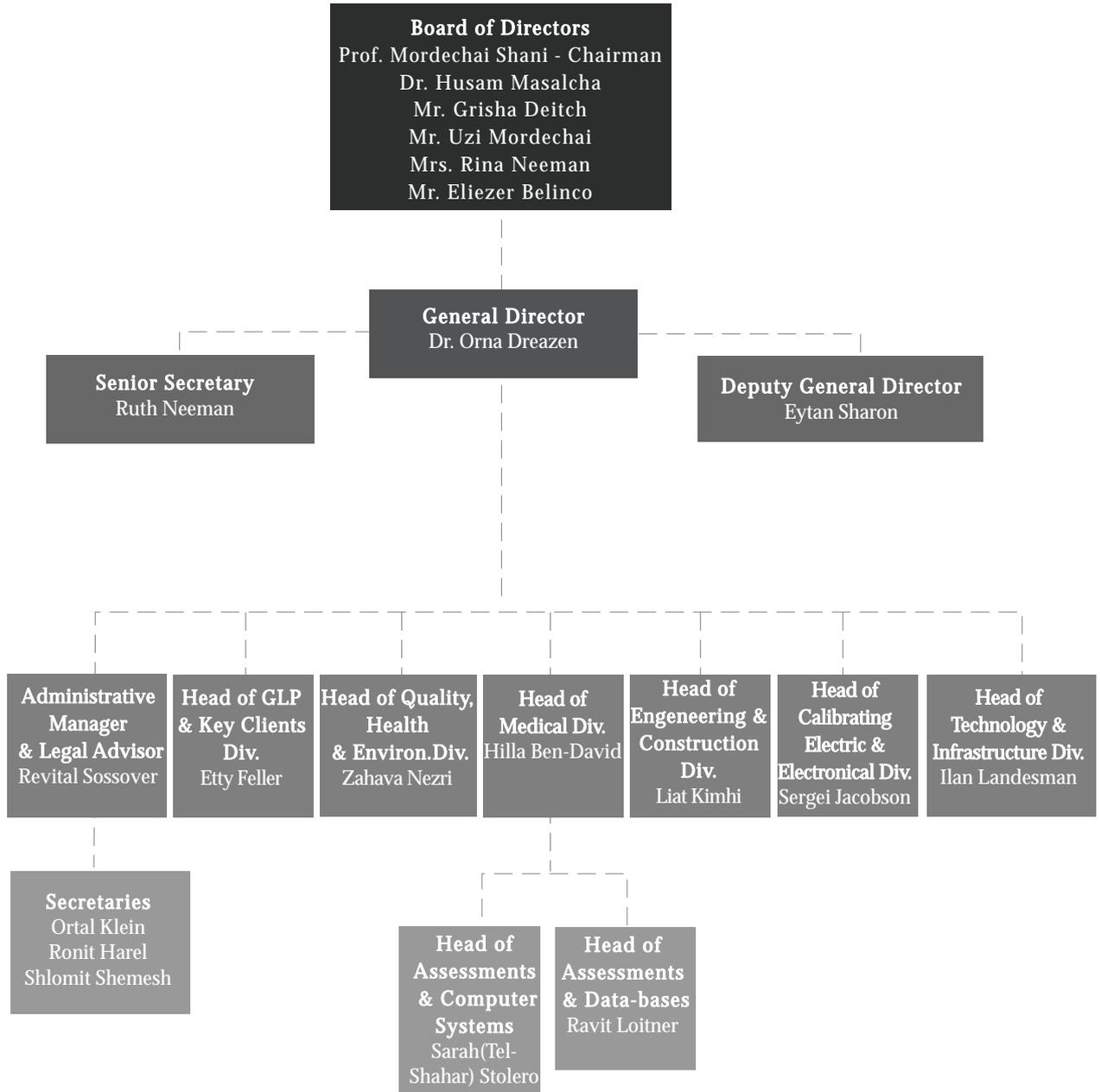
I am sure that ISRAC will succeed in its missions by combining the enthusiasm and passion that characterized the activity in the past with the accumulated knowledge in quality and specific professional areas.

Eytan Sharon

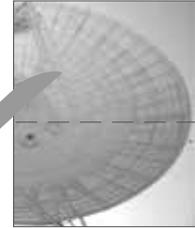




Organization chart



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 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 34 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 2003 six 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

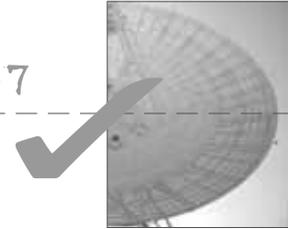
Laboratory accreditation may be provided for any type of properly documented test, measurement or calibration. At present, ISRAC accredits for the following types of tests / calibrations:

### 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, based on its clients' needs and on the decisions of ISRAC's board.

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

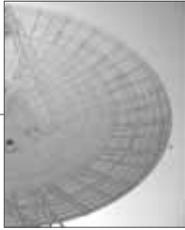
## Requirements for an Accreditation

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.



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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 34 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:

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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)

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## Main activities during 2007



Last year we set ourselves the following goals:

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

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 spirit in the draft of the revised law is to focus more on accreditation that is regulation oriented (Certification of personnel and Inspection bodies). The Industry Association requested the Israc's accreditation scope would include also unregulated professions.

The revision of the law is now in its final draft. The final draft considers also the implications of the experience gained from the withdrawal of accreditation from one of the building laboratories. The implications deal with the required tools that would enable ISRAC to function in cooperation with and for various regulators.

We hope that in the year of 2008 the revised law would be submitted to the parliament's approval.

### Emphasizing the Uncertainty issue

An uncertainty exists in all measurement results in all areas. This uncertainty actually expresses the range that is reasonable to assume that the "true" result is somewhere in that range. This uncertainty is obviously different in different areas, different laboratories and different tests. For various reasons,

the decisions makers in many areas in Israel and other countries did not give this issue enough attention.

The accreditation standards for laboratories request that each accredited laboratory shall have an estimation for the uncertainty of each accredited test. These uncertainties should have a sound base. ISRAC's assessors checked this issue as a key subject in the year 2007.

ISRAC gave many workshops on this matter to promote awareness and to provide tools for uncertainty estimation.

### New activity areas

An extensive work with Israeli water commission to accredit water gages testing facilities came to a happy end. The accreditation process has began in several independent test facilities and several plants test facilities.

### Accreditation of new laboratories

12 new laboratories were accredited in 2007.

The total number of accredited organization at the end of 2007 has reached 109. The number of accredited organization at the end of 2006 was 97. No significant breakthrough in the number of accredited medical laboratories happened in 2007 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 CEO of ISRAC has been a member of ILAC executive committee for the last six years and the Chairperson in the ARC international committee of ILAC. Within this framework, the CEO is involved through ILAC in the work of ISO/CASCO, WHO, WTO, IAF, BIPM and the European Common Market.

The deputy of the CEO took part in the Quality standard committee at SII.

The deputy of the CEO is a member in the management of the Israeli Society for Quality and the Chairman of its Ethics committee.



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Governmental office	Laboratory services	Requires accreditation	Ministerial laboratories are accredited
Ministry of Health	Water and food, pesticides, private clinical labs	✓ -	✓
Ministry of Agriculture	Pesticides, Remnants of pesticides (required for export)	- ✓	✓ ✓
Ministry of Defense	All fields	✓	Preliminary labs were accredited in the air force
Ministry of Trade, Labor & Industry	Commissioner of standard Radiation	✓ ✓	No labs No labs
Ministry of Trade, Labor & Industry	Hygienic employment Noise	From June 2006 From December 2006	In process
Ministry of Justice	Electronic signature	✓	No labs
Ministry of Environment	Radiation Soil, waste, flammables Environment	In process ✓ ✓	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 Geology	✓ ✓ ✓ -	-
Communications	Equipment - import	-	-
Transportation	Vehicles	-	No labs
Ministry of Housing and Construction	Construction	✓	No labs



## Cooperation with International Accreditation and Certification Organizations

ISRAC representatives participate in the activities of the following organizations:

- EA (European Accreditation)
- ILAC (International Laboratory Accreditation Cooperation)
- OECD (Organization of Economic Cooperation and Development) In the field of GLP (Good Laboratory Practice).

The General Director of ISRAC has finished her 6th year as a member of the ILAC Executive committee and in the last two years as the head of the Arrangement Committee of the organization. In this position the General Director works with ISO/CASCO, WHO, WTO, IAF, BIPM and many more, representing ISRAC and Israel.

## Raising the awareness for Metrology

ISRAC personnel work to raise the awareness for Metrology. The activities are performed in many different fields that all contribute on different levels and target different audiences. Below are several of the methods used to obtain this goal:

- Giving courses in Metrology at the ISRAC training center and the different Universities in Israel.
- Publishing articles in the Scientific and Popular

- papers.
- Extensive work with regulators and central buyers in order to create demand for accurate measurement.
- Activity on International Standardization committees which create laboratory and industrial standards and statement papers regarding measurement and the implementation of the importance of it in standardization.
- Submitting Statement papers to the court regarding issues of measurement.
- Work with laboratories and ISRAC assessors in order to improve their knowledge in Metrology.
- A meeting of the ILAC executive committee in Tel-Aviv and a Metrology convention in coordination with the Israeli Export institute.

## Raising the number of accredited organizations and technologies

During the year 2006 16 new organizations were accredited for 40 new technologies. The total number of accredited organizations on 2006 was 97, while the number at the end of 2005 was 82 organizations. The accreditation process of a laboratory is long and usually requires a significant upgrading of the laboratory; therefore the small increase in the number of accredited laboratories reflects the difficulty and thoroughness of the process.

## The main activities planned for the year 2008

- Approval of the ISRAC law.
- Broadening the cooperation between ISRAC and all regulators.
- Cooperation with international accreditation and standardization organizations.
- Heightening the awareness for metrology.
- Increasing the number of accredited organizations and technologies.
- Broadening the cooperation with the consumer organizations, the industrial union, the export institute and the chambers of commerce.



# Annual Report 2007

## Budget for 2007 and 2008



### Budget for 2007 and 2008

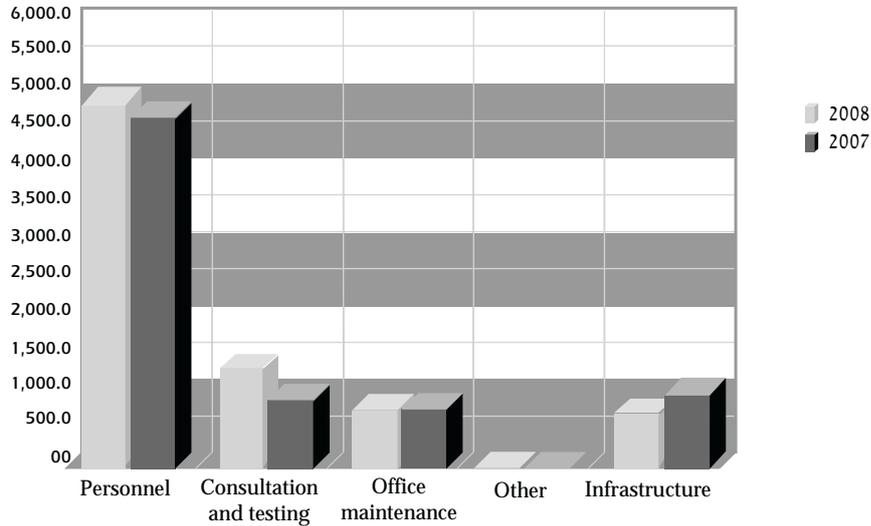
	2007 budget	2008 budget	Nominal Change
	NIS 000's	NIS 000's	%
<b>Expenditure</b>			
Regular operations	4,149.8	4,688.3	13.0
Development	3,713.1	3,606.9	-2.9
<b>Total Expenditure</b>	<b>7,862.9</b>	<b>8,295.2</b>	<b>5.5</b>
<b>Income from Operations</b>			
Accreditation and surveillance	3,447.0	3,725.7	8.1
Training and GLP inspections	300.0	250.0	-16.7
<b>Total Income from Operations</b>	<b>3,747.0</b>	<b>3,975.7</b>	<b>6.1</b>
<b>Income from Funding</b>			
Funding of development - State budget	3,713.1	2,812.8	-24.2
Regular funding - State budget	273.9	0.0	-100.0
Preceding Year's Surplus	128.9	1,406.5	991.3
Income from interest		100.0	
<b>Total Income from Funding</b>	<b>4,115.9</b>	<b>4,319.5</b>	<b>4.9</b>
<b>Total Income</b>	<b>7,862.9</b>	<b>8,295.2</b>	<b>5.5</b>

### Expenditure

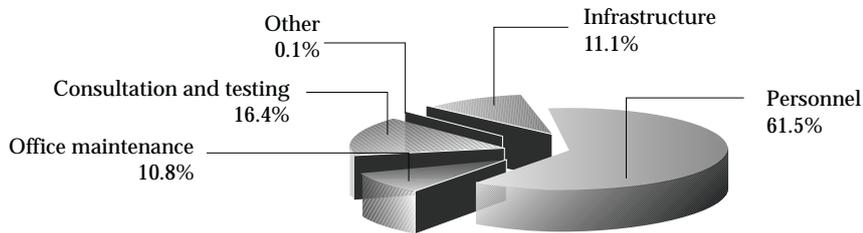
		2007 budget	2008 budget	Nominal Change
		NIS 000's	NIS 000's	%
<b>Expenditure</b>				
1.0	Personnel	4,937.6	5,102.1	3.3
2.0	Consultation and testing	987.1	1,364.2	38.2
3.0	Office maintenance	881.8	898.9	1.9
4.0	Other	5.0	5.0	0.0
	<b>Total operating expenditure</b>	<b>6,811.5</b>	<b>7,370.2</b>	<b>8.2</b>
	Development element	-2,661.7	-2,692.1	1.1
	<b>Total regular operations</b>	<b>4,149.8</b>	<b>4,678.1</b>	<b>12.7</b>
5.0	Infrastructure	1,051.4	924.8	-12.0
	Development components	2,661.7	2,692.1	1.1
	<b>Total development</b>	<b>3,713.1</b>	<b>3,616.9</b>	<b>-2.6</b>
	<b>Total</b>	<b>7,862.9</b>	<b>8,295.0</b>	<b>5.5</b>



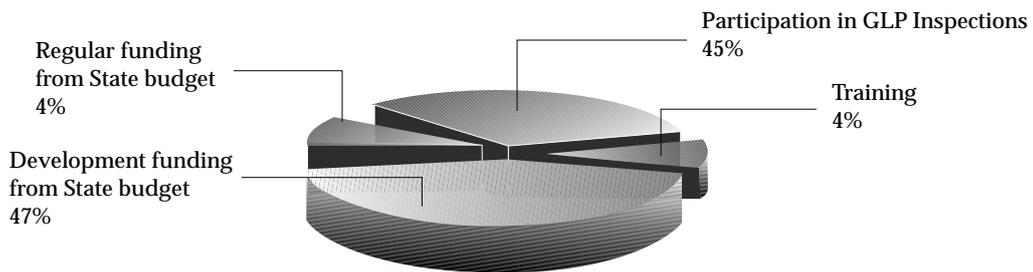
Forecast of Expenditure in the 2008 Budget in Comparison with the 2007 Budget:



Breakdown of Expenditure in 2007



Breakdown of Income in 2007

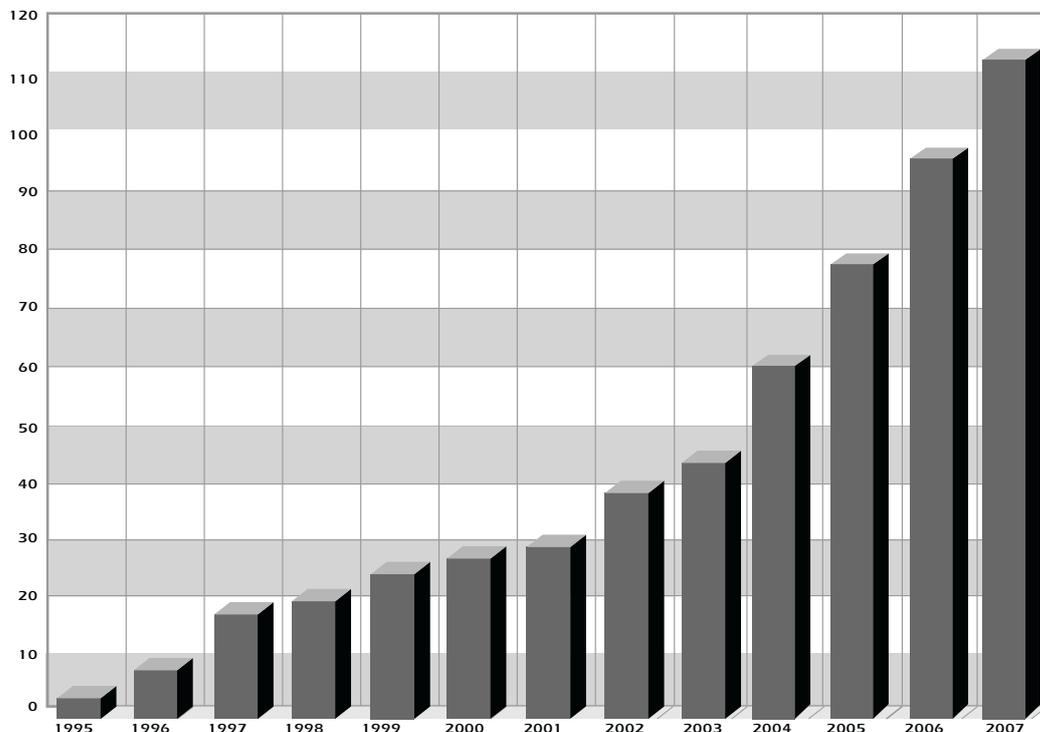


As of January 2008, 99 laboratories have received accreditation, and 8 research facilities received recognition to GLP. 29 laboratories are in the process of accreditation.

Department	No. of accredited labs.	No. of labs. in the process of accreditation
Engeneering	22	4
Health & Environment	18	3
Strategic Clients	22	1
Medical	11	2
Electric & Electronics	17	8
Infrastructure	9	11
GLP (accreditation)	8	0



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.