



Ministry of Industry, Trade & Labor



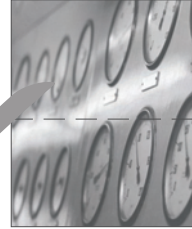
ISRAC
Israel Laboratory Accreditation Authority



Annual Report

Year
2008





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Ten years have passed since the Israeli Accreditation Authority for laboratories (ISRAC) was established by law.

The ISRAC law defines ISRAC's mission, role and tasks.

During those ten years, ISRAC became a significant partner in the Israeli regulatory infrastructure and also gained international recognition and respect.

ISRAC activity in accreditation of laboratories according to international standards of competence enhance the ongoing mission of implementing quality in Israel.

ISRAC activity continuously increased the circles of users who enjoy more controlled better products and services.

ISRAC council nominated according to the law, together with ISRAC's professional staff, work consistently to promote ISRAC's national mission to act as the designated body to accredit and control governmental as well as private laboratories at various areas of Israel economy.

ISRAC managers have unrelentingly lead ISRAC at the past and the present to international recognition of EA and ILAC.

Their efforts got ISRAC its position as integral part of worldwide network of laboratory accreditation bodies.

There is no doubt that ISRAC laboratory accreditation is a significant asset in the state of Israel which helps domestic and international economic activities by providing a tool for the Israeli industry. After ten years of activity I look back in satisfaction to ISRAC's achievements and call for governmental and private organizations to increase the use of ISRAC's services.

I am convinced in the added value of ISRAC activities to its various customers and stakeholders in Industry, building projects, medical areas, etc.

There is no doubt that increasing use of ISRAC's services would improve the quality of life in Israel.

Uzi Mordechai



I quote a phrase from the ISO 9000 standard: "Effective decisions should be based on analysis of data and information".

The decision makers should base decisions on data but on occasions they do not have the tools to check the quality of those data.

Many decisions are based on laboratories results.

An effective tool to have confidence in the data provided by the laboratory is accreditation by an accreditation body.

The meaning of accreditation is that an impartial and competent body checked carefully and thoroughly the laboratory prior to its accreditation. Therefore, the results of the laboratory are trustworthy. During the last years, more regulators, worldwide and domestic, are convinced in the cost effectiveness of laboratories accreditation.

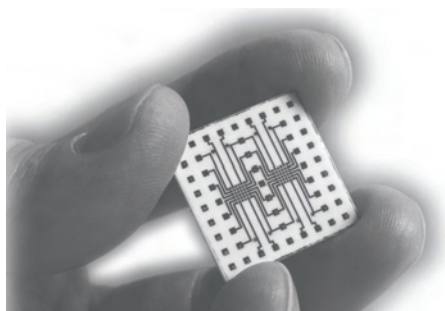
ISRAC continued its activity in all the areas despite of the personal changes in the board of directors and senior management, that occurred on 2008.

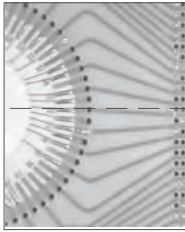
I am convinced that the excellent experienced team and the new persons who came on board will continue successfully the good work of ISRAC.

On November 2008 EA team assessed ISRAC in its inspection and Testing activities. The assessment was successful.

The Calibration area is due to be assessed on beginning of 2010.

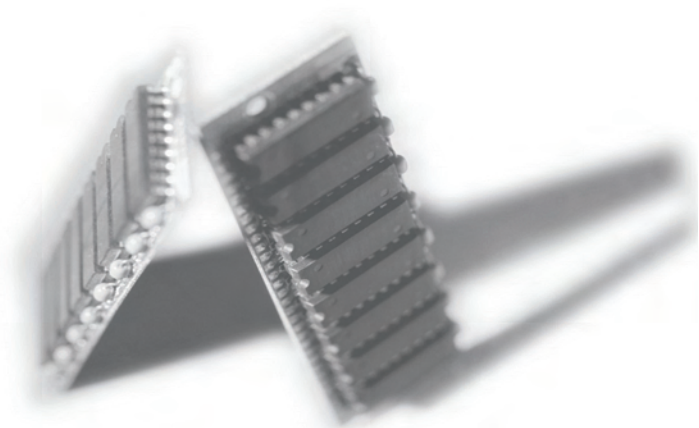
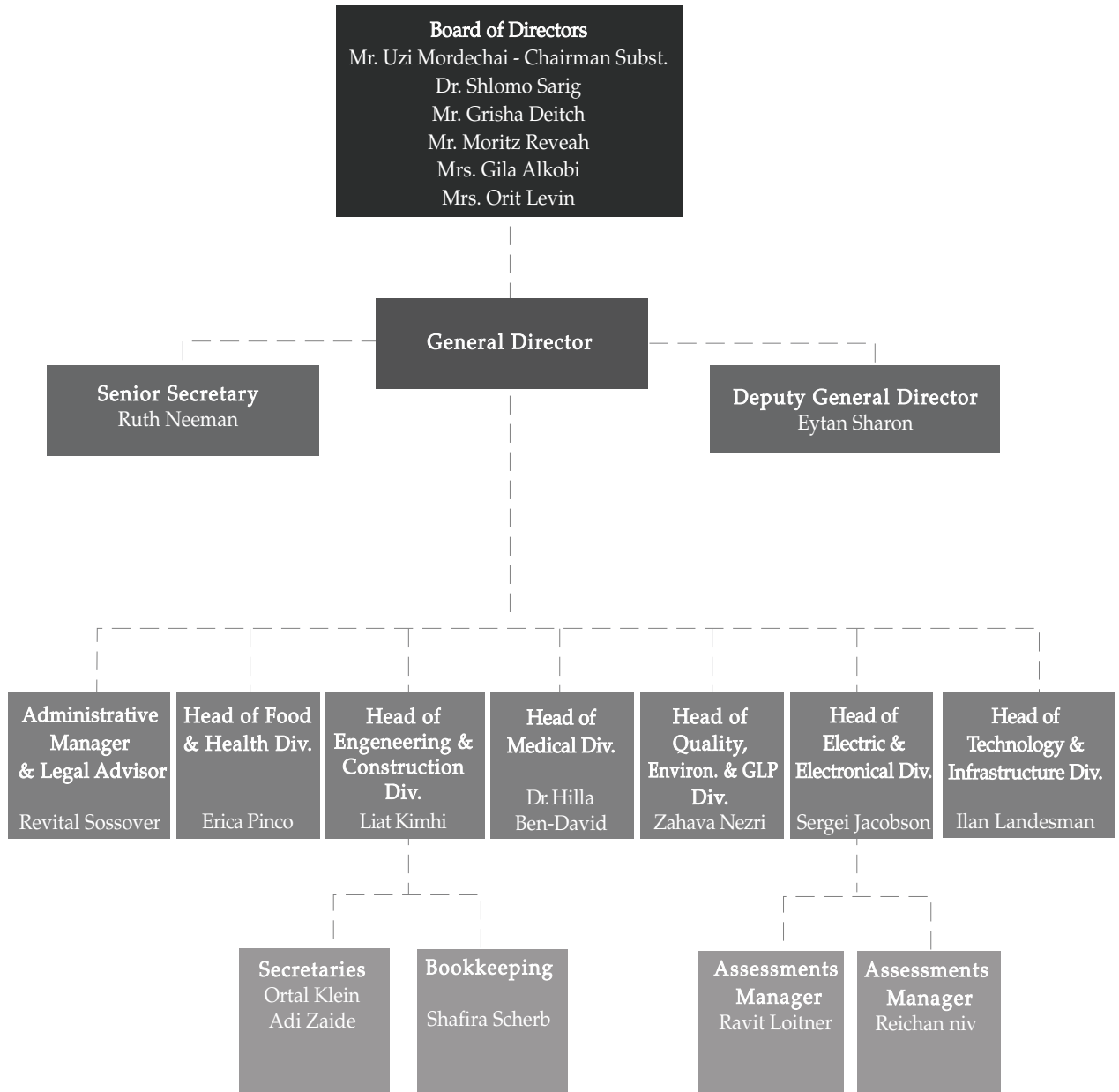
Eytan Sharon

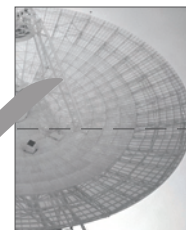




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Organization chart





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.

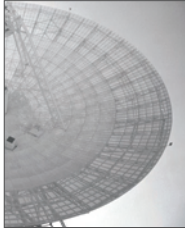
In 1992, in preparation for the establishment of an accreditation system in Israel, meeting international standards and gaining international recognition, the minister of industry and trade appointed a committee to examine the issue of the accreditation of laboratories.

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

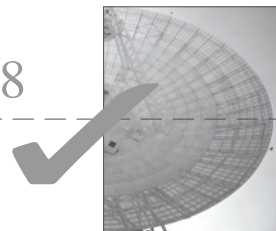
Laboratory accreditation may be provided for any type of properly documented test, measurement or calibration. At present, ISRAC accredits for the following types of tests / calibrations:

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

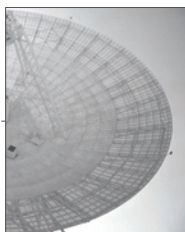
Requirements for an Accreditation

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.
- 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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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. ISRAC team hope that the new minister, Mr. Fuad Ben Eliezer and his deputy Mrs. Orit Noked, will push forward the procedure to the benefit of the regulators and the public.

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. On 2008, 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.

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

19 new laboratories were accredited in 2008. The total number of accredited organisation at the end of 2008 has reached 116. The number of accredited organization at the end of 2007 was 106. No significant breakthrough in the number of accredited medical laboratories happened in 2008 in spite of the fact that this area has a great potential.

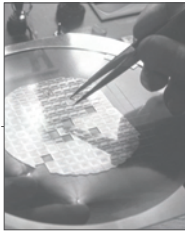
Cooperation with international accreditation and standardization organizations

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

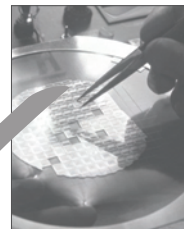
The deputy of the CEO is a member in the management of the Israeli Society for Quality and the Chairman of its Ethics committee.



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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



►►► The main activities planned for the year 2009



- Approval of the ISRAC law.
- Broadening the cooperation between ISRAC and all regulators.
- Cooperation with international accreditation and standardization organizations.
- Heightening the awareness for uncertainties in measurements with special emphasis on uncertainty in sampling.
- 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.



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Budget for 2008 and 2009



Budget for 2008 and 2009

	2008 budget	2009 budget	Nominal Change
	NIS 000's	NIS 000's	%
Expenditure			
Regular operations	4,688.3	4,640.9	-1.0
Development	3,606.9	3,454.9	-4.2
Total Expenditure	8,295.2	8,095.8	-2.4
Income from Operations			
Accreditation and surveillance	3,725.7	3,498.0	-6.1
Training and GLP inspections	250.0	200.0	-20.0
Total Income from Operations	3,975.7	3,698.0	-7.0
Income from Funding			
Funding of development - State budget	2,812.8	3,527.0	25.4
Regular funding - State budget	0.0	0.0	0.0
Preceding Year's Surplus	1406.5	845.8	-39.9
Income from interest	100.0	25.0	
Total Income from Funding	4,319.5	4,397.8	1.8
Total Income	8,295.2	8,095.8	-2.4

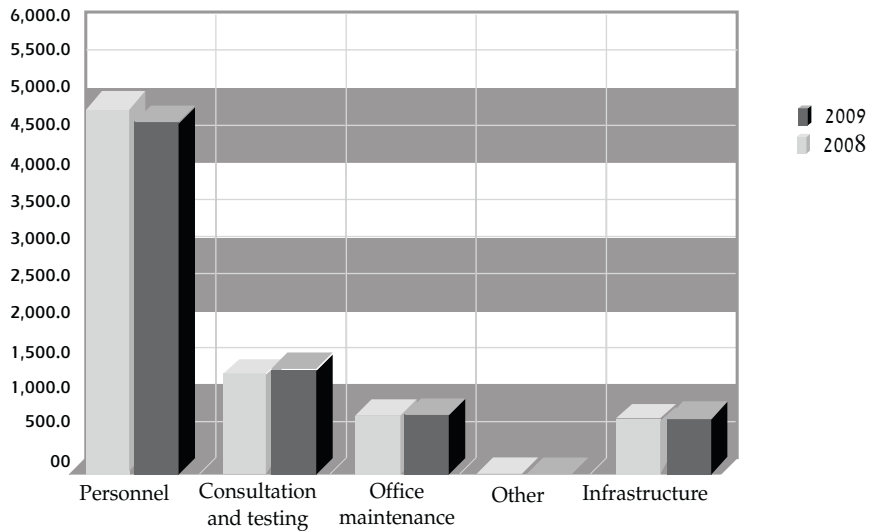
Expenditure

		2008 budget	2009 budget	Nominal Change
		NIS 000's	NIS 000's	%
Expenditure				
1.0	Personnel	5,102.1	4,831.0	-5.3
2.0	Consultation and testing	1,364.2	1,401.7	2.7
3.0	Office maintenance	898.9	909.3	1.2
4.0	Other	5.0	8.0	60.0
	Total operating expenditure	7,370.2	7,150.0	-3.0
	Development element	-2,692.1	-2,517.1	-6.5
	Total regular operations	4,678.1	4,632.9	-1.0
5.0	Infrastructure	924.8	945.8	2.3
	Development components	2,692.1	2,517.1	-6.5
	Total development	3,616.9	3,462.9	-4.3
	Total	8,295.0	8,095.8	-2.4

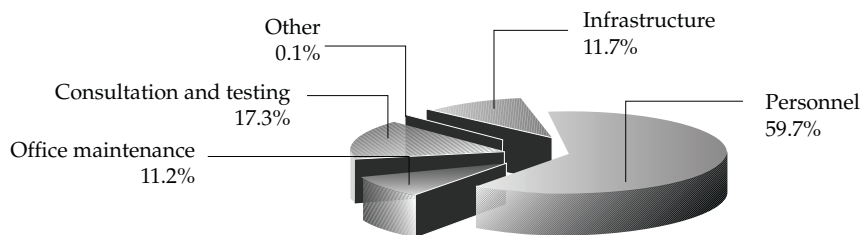
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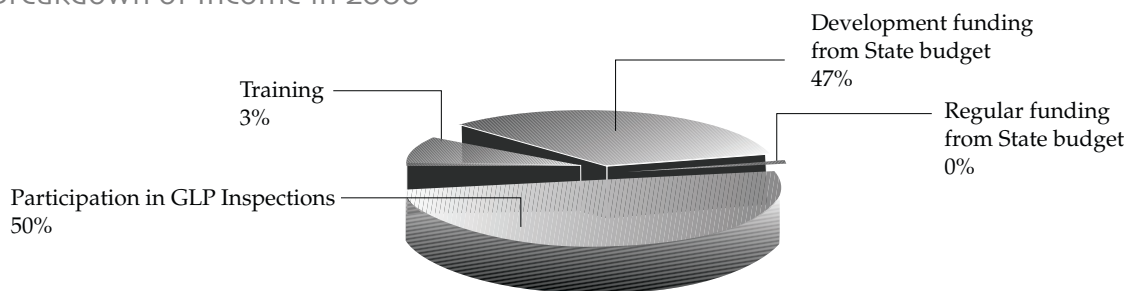
Forecast of Expenditure in the 2009 Budget in Comparison with the 2008 Budget:



Breakdown of Expenditure in 2008



Breakdown of Income in 2008



As of January 2009, 99 laboratories have received accreditation, and 8 research facilities received recognition to GLP. 29 laboratories are in the process of accreditation.

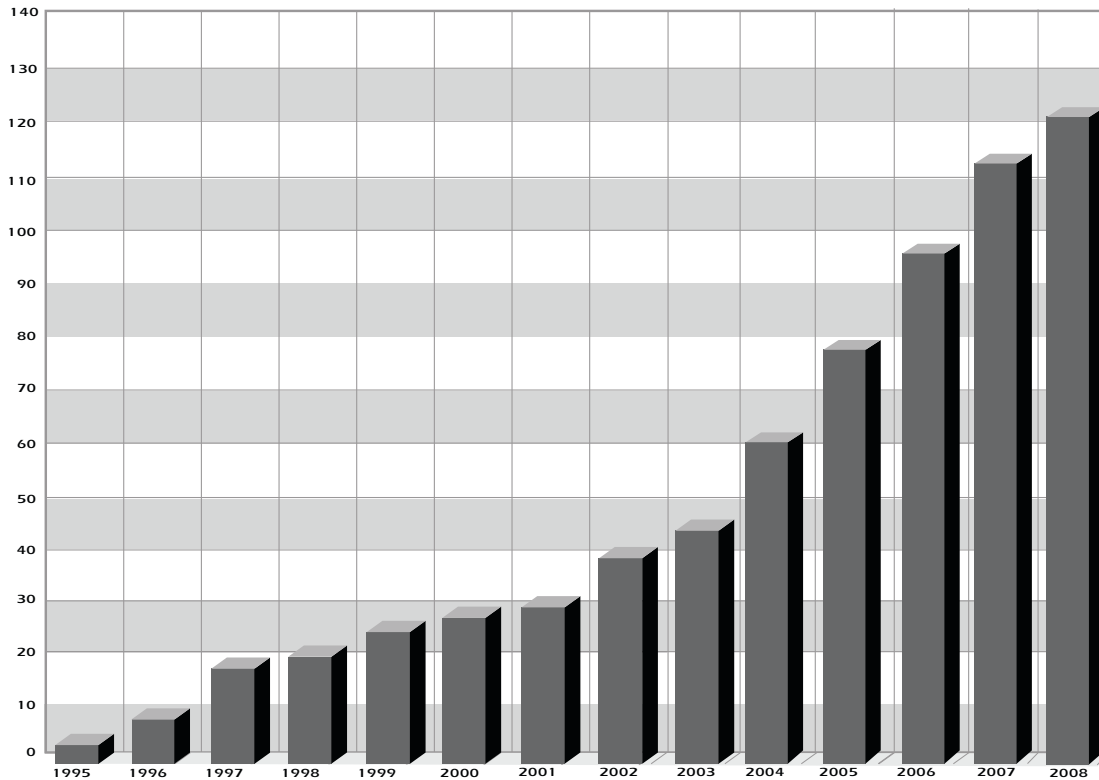
Department	No. of accredited labs.	No. of labs. in the process of accreditation
Engeneering	23	1
Health & Environment	21	4
Strategic Clients	22	0
Medical	13	0
Electric & Electronics	20	8
Infrastructure	16	9
GLP (accreditation)	9	2



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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.