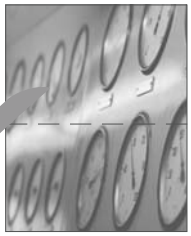
Ministry of Industry, Trade & Labor

ISRAC
Israel Laboratory Accreditation Authority

Annual Report

Year 2006



Contents

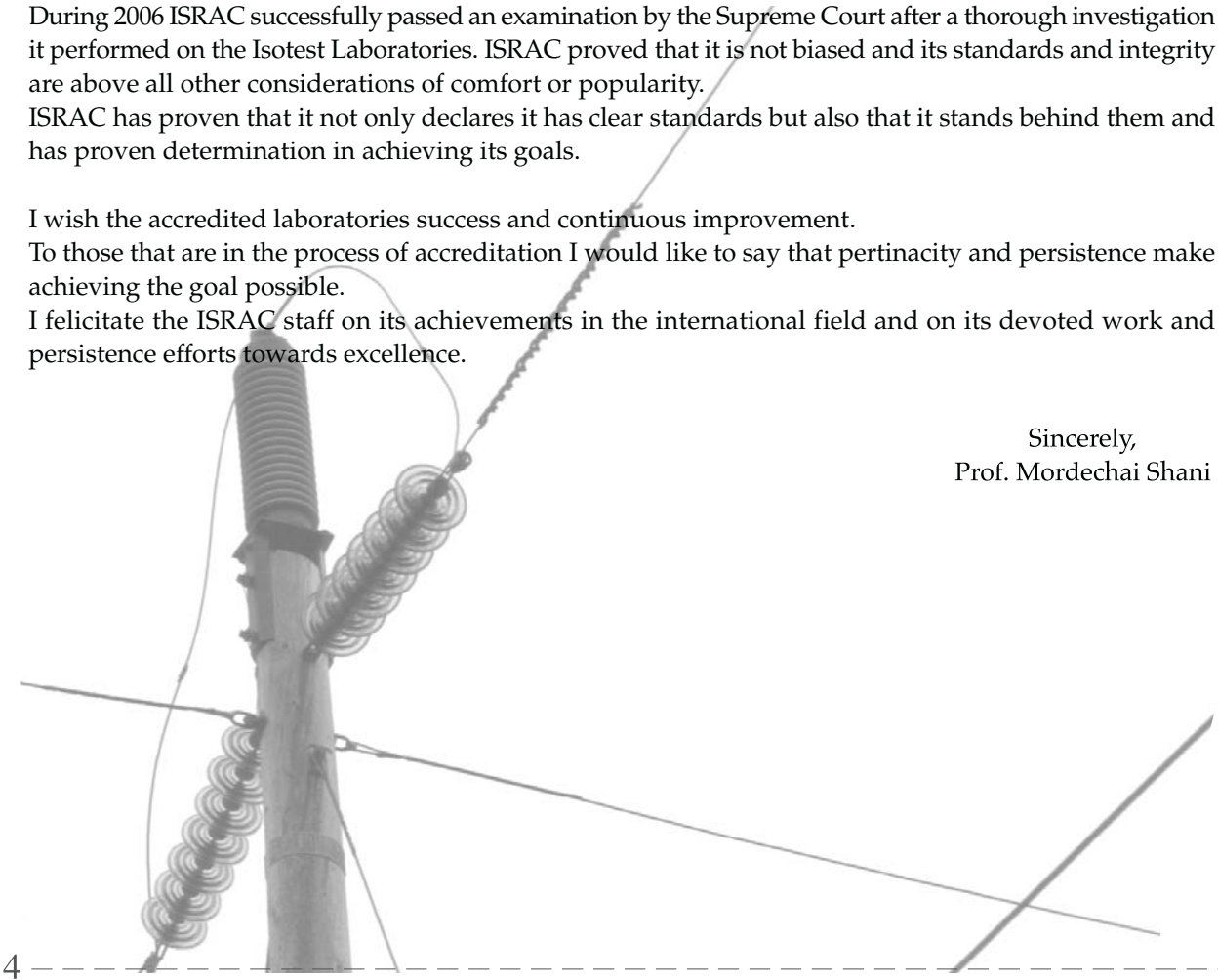
From the Chairman of the Council

The Israel Laboratory Accreditation Authority (ISRAC) was established in 1997 as a national infrastructure, for the good of the Israeli public. This public includes laboratory customers that depend daily on the laboratory's measurement and testing services, and the industry, which produces products for the national and international market.
ISRAC has assigned top priority to medical, safety and environmental issues and has therefore invested much work, during the past year, on broadening the knowledge and allowing for the accreditation of laboratories in these fields.
The Strict upholding of high standards in all its areas of work is one of the central obligations and identifying marks of any modern country. The first rule for upholding standards is the training of conformity assessment bodies and the adjustment of their standards to the international ones and to national requirements. That is the role of ISRAC and it is its intention to broaden the number of accredited laboratories in Israel in many different and diverse fields.
In the year 2006 ISRAC has broadened its cooperation with most of the regulatory authorities in Israel. Many public laboratories have been accredited or have begun the accreditation process. The state of ISRAEL thus ensures its citizens that its decision making process is based on valid and trustable information.

We are now working on broadening the scope of ISRAC to include accreditation of all certification activities. We hope to fulfill this plan by updating the Israel Accreditation Authority law.
During 2006 ISRAC successfully passed an examination by the Supreme Court after a thorough investigation it performed on the Isotest Laboratories. ISRAC proved that it is not biased and its standards and integrity are above all other considerations of comfort or popularity.
ISRAC has proven that it not only declares it has clear standards but also that it stands behind them and has proven determination in achieving its goals.

I wish the accredited laboratories success and continuous improvement.
To those that are in the process of accreditation I would like to say that pertinacity and persistence make achieving the goal possible.
I felicitate the ISRAC staff on its achievements in the international field and on its devoted work and persistence efforts towards excellence.

Sincerely,
Prof. Mordechai Shani



From the General Director

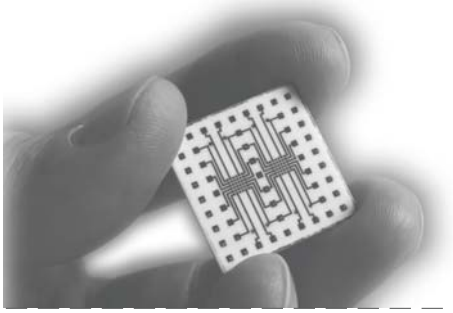
Israel Laboratory accreditation authority grants accreditation only if the management of the laboratory is deemed trustworthy and can be counted on to fulfill its obligations towards itself and ISRAC, to constantly reviewing its performance and is involved in continues improvement. In addition it is necessary for the management and employees to exhibit high professional competence when performing the activities for which they have been accredited.

The year 2006 was a defining year for the Israel Laboratory Accreditation Authority. For the first time, after ten years of activity, the accreditation of a big lab in the field of engineering was suspended. The suspension was preceded by a thorough investigation performed by the ISRAC staff, including unannounced assessments, regular assessments and questioning of many people. The investigation was carried out in order to evaluate whether the suspected normative failures were caused by corruption of individuals in the laboratory or are a result of a systematic failure. The investigation was carried out by the limited means granted to ISRAC by the law, without the aid of any regulator, which has legislative and investigation capabilities and does not require the cooperation of the laboratory. Despite its limited means, the ISRAC staff proved that a widespread failure existed in the lab and was supported by its management. The laboratory was given the opportunity to present its arguments before a Hearing committee, which finally concluded that a widespread systematic failure did exist in the lab. Recently, several indictments were submitted against some of the laboratory's managers and employees. These events have allowed ISRAC to prove that it requires high ethical and professional norms and does not hesitate to take steps against those that do not uphold them.

ISRAC performs its work in the field of engineering as the basis for the recognition of the laboratories by the regulator. Therefore, in this case ISRAC acted on behalf of the state.
These circumstances have elucidated **the need for a strong ISRAC that is independent of its clients** and does not hesitate to engage in costly activities, even at the price of loosing a client, if they are not dictated by the high ethical, moral and professional standards set by ISRAC.

ISRAC employees, I would like to thank you for the devotion and effort you have invested in your work due to the need for budgetary cuts.

Dr. Orna Dreazen



Organization chart

Board of Directors
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Mr. Grisha Deitch
Mr. Uzi Mordechai
Mrs. Rina Neeman
Mr. Eliezer Belinco

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Deputy General Director
Eytan Sharon

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Etty Feller

Head of Quality, Health & Environment Div.
Zahava Nezri

Head of Medical Div.
Hilla Ben-David

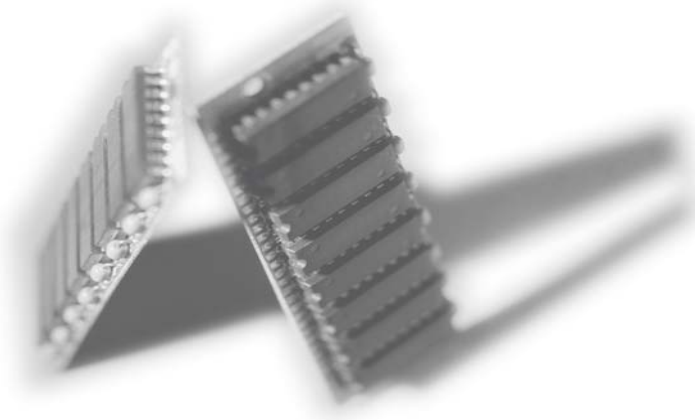
Head of Engeneering & Construction Div.
Liat Kimhi

Head of Calibrating Electric & Electronical Div.
Sergei Jacobson

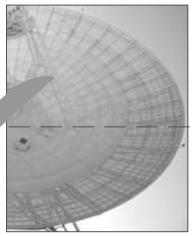
Secretaries
Ortal Klein
Ronit Harel
Shlomit Shemesh

Head of Assessments & Computer Systems
Ilanit Broide

Head of Assessments & Data-bases
Ravit Loitner



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 harmoniztion 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 recerve 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 pharmaceutics, 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

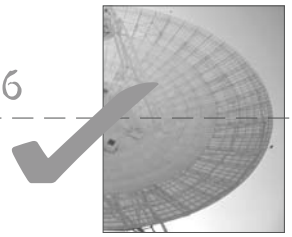
Laboratory accreditation may be provided for any type of properly documented test, measurement or calibration. At present, ISRAC accredits for the following types of tests / calibrations:

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

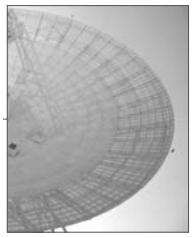
Requirements for an Accreditation

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.



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.

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Main activities during 2006

Last year we set ourselves the following goals:

- Approval of the ISRAC law.
- Strengthening the cooperation between ISRAC and the regulators in all governmental offices.
- Cooperation with International accreditation and standardization organizations.
- Raising the awareness regarding metrology.
- Increasing the number of accredited organizations and technologies.
- Strengthening the cooperation with the Manufacturers Association of Israel, consumer organizations, the export institution and the bureau of commerce.

All goals that rely solely on ISRAC have been achieved. However, some depended on cooperation with others were not fully achieved.

Approval of the ISRAC law

The work on this goal is still in progress. The political reality did not make it possible to finalize the law, last year. However, the legal department of the Ministry of Trade, Labor & Industry published a detailed document describing the need of the state of a second authority to increase the enforcement of regulation on the economy. Following the publishing of this document, discussions were held between the legal department of the Ministry of Trade, Labor & Industry and the Ministry of Justice. At the moment a proposition is being worded according to which ISRAC shall perform accreditations, mainly for purposes of regulation (in the areas of professional personnel certification and examination, inspection and surveillance bodies). Due to the Manufacturers Association's request, it may be possible that ISRAC shall also undertake the accreditation of Certification bodies of professional personnel in areas not regulated by the state.
The law is at the final stages of work.
A few implications of the suspension of the accreditation of the Isotest lab on the tools needed by ISRAC in the performance of its duties with and for different regulators were studied and integrated in the proposed law. We hope that during the year 2007 the Law proposal shall be presented before the Knesset.

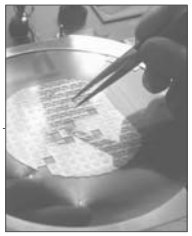
A Test of the Strength and Competence of ISRAC

At the end of 2005 ISRAC received several complaints regarding the Isotest laboratory, regarding its working procedures and its integrity. ISRAC performed an investigation during a period of 3 months, about 50 work days. During the investigation ISRAC personnel was convinced that a systemic problem indeed exists in the system. Despite the fact that ISRAC personnel do not have investigational tools and authority, a thorough investigation was performed. During the investigation many details proving a severe problem surfaced. These assessments required a concentrated effort and included areas that are not in the normal scope of ISRAC.

In order to avoid all insinuations regarding our integrity or economic interests, all the investigation and on going processes were financed by ISRAC. When the investigation was through, a hearing procedure was held, according to the ISRAC law. External lawyers, headed by Mrs. Miriam Rosenthal formally the district attorney of the Tel-Aviv district, were contracted for the hearing procedure, in order to ensure ISRAC's integrity and in case the matter may reach the Supreme Court.

The hearing procedure was completely transparent and the lab was given three opportunities in which they presented their arguments. The hearing committee was convinced by the evidence that there was a systemic failure in the lab that required the suspension of its accreditation.
The next step in the process was the decision of the Supreme Court. The Supreme Court lawyers were convinced that the failure observed in the lab's work indeed justified the measures taken by ISRAC. The Supreme Court judges approved of the entire procedure and the fairness and objectivity of ISRAC.

ISRAC passed a second examination in the Labor Court. One of the employees of the Isotest lab sued ISRAC and its General Director because the lab threatened to fire him. As in the Supreme Court the judge in this case also approved ISRAC's actions and that the suit was not justified.



Broadening the cooperation between ISRAC and all regulators

ISRAC works in cooperation with regulators from many different governmental offices. The degree of involvement with the different regulators is determined according to their needs, resources and knowledge available to them.
This year we created in cooperation with the Water Authority a list of requirements for bodies involved in the calibration of water meters and next year we shall begin the training and accreditation of their employees according to this list.
In addition, we have deepened our cooperation with the work supervisor in the Ministry of Trade, Labor & Industry in the field of the assessment of labor safety and hygiene and we are working on additional fields such as noise level testing.
The requirements for these accreditations have been established in cooperation with the unit for of labor safety and hygienic employment in the Ministry of Trade, Labor & Industry.
The department for the licensing of security industries in the Ministry of Internal affairs together with the representatives of the different governmental offices has announced that beginning from the 1.1.2006 only the results of accredited laboratories will be accepted when applying for a license.
The cooperation with the department of legal metrology was also broadened in the past year in order to set the requirements for laboratories and testing facilities that approve a standard. Following is a table containing the fields in which different regulators use the services of ISRAC.

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 2007

- 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.

Budget for 2006 and 2007

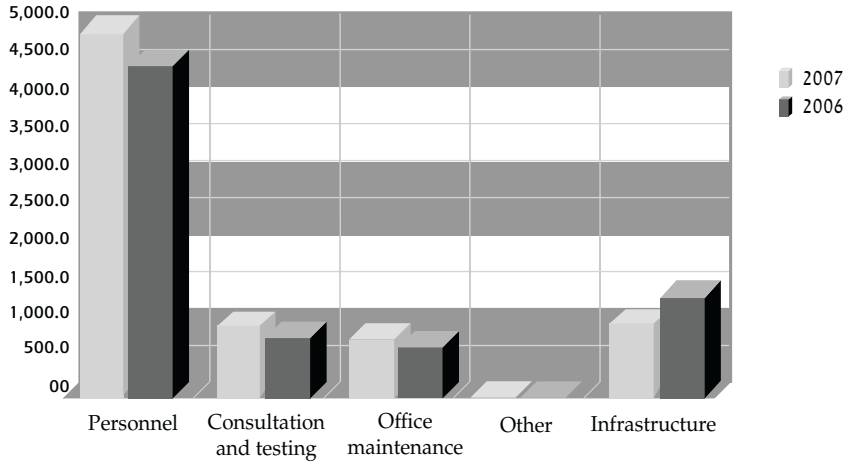
Budget for 2006 and 2007

	2006 budget	2007 budget	Nominal Change
	NIS 000's	NIS 000's	%
Expenditure			
Regular operations	3,888.9	4,149.8	6.7
Development	3,711.1	3,713.1	0.1
Total Expenditure	7,600.0	7,862.9	3.5
Income from Operations			
Accreditation and surveillance	3,126.0	3,447.0	10.3
Training and GLP inspections	360.0	300.0	-16.7
Total Income from Operations	3,486.0	3,747.0	7.5
Income from Funding			
Funding of development - State budget	3,711.1	3,713.1	0.1
Regular funding - State budget	402.9	273.9	-32.0
Preceding Year's Surplus	0	128.9	
Total Income from Funding	4,114.0	4,115.9	0.0
Total Income	7,600.0	7,862.9	3.5

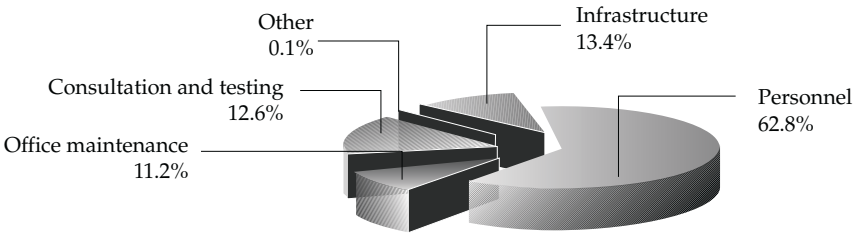
Expenditure

		2006 budget	2007 budget	Nominal Change
		NIS 000's	NIS 000's	%
Expenditure				
1.0	Personnel	4,577.0	4,937.6	7.9
2.0	Consultation and testing	899.0	987.1	9.8
3.0	Office maintenance	830.0	881.8	6.2
4.0	Other	5.0	5.0	0.0
	Total operating expediture	**6,311.0**	**6,811.5**	**7.9**
	Development element	-2,422.1	-2,661.7	9.9
	Total regular operations	**3,888.9**	**4,149.8**	**6.7**
5.0	Infrastructure	1,289.0	1,051.4	-18.4
	Development components	2,422.1	2,661.7	9.9
	Total development	**3,711.1**	**3,713.1**	**0.1**
	Total	**7,600.0**	**7,862.9**	**3.5**

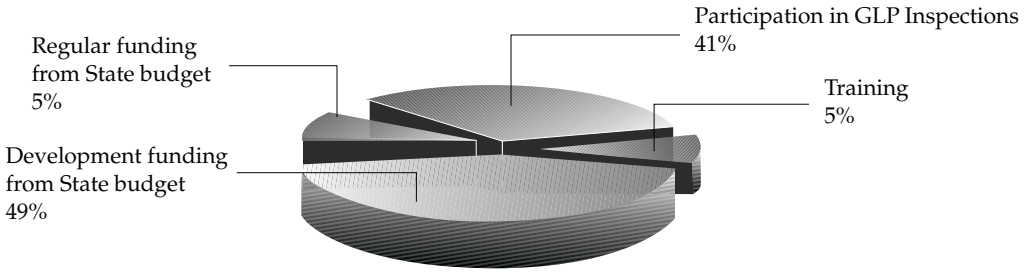
Forecast of Expenditure in the 2007 Budget in Comparison with the 2006 Budget:



Breakdown of Expenditure in 2006



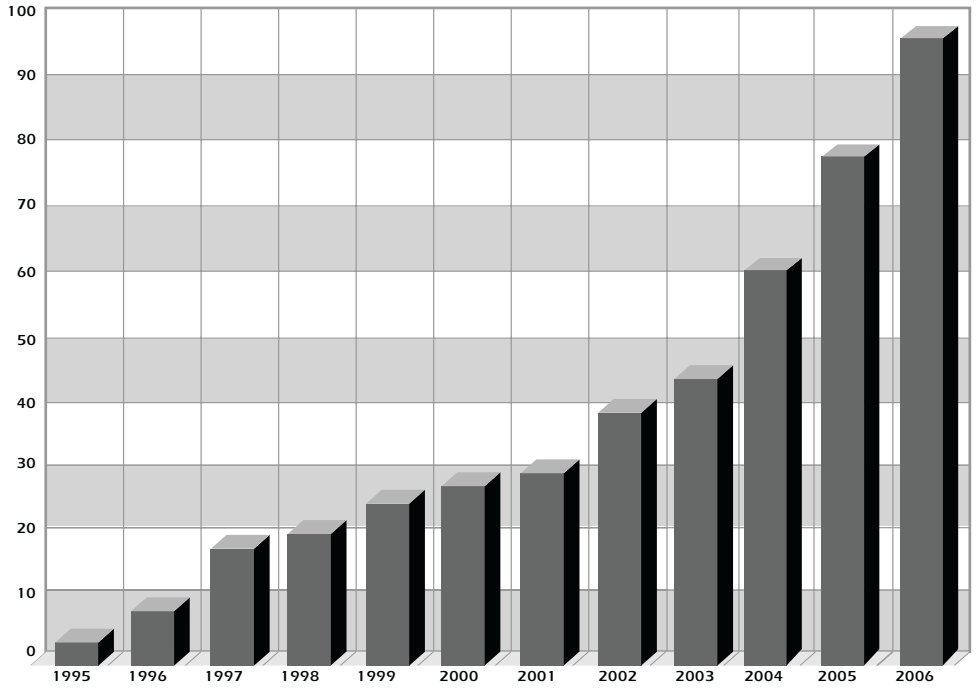
Breakdown of Income in 2006



As of January 2007, 89 laboratories have received accreditation, and 8 research facilities received recognition to GLP. 22 laboratories are in the process of accreditation.

Department	No. of accredited labs.	No. of labs. in the process of accreditation
Engeneering	18	8
Health & Environment	17	3
Strategic Clients	18	6
Medical	11	0
Electric & Electronics	17	4
Infrastructure	8	1
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).

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 thier 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.