



Ministry of Industry, Trade & Labor



ISRAC
Israel Laboratory Accreditation Authority



Annual Report

Year
2005





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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 invested much, during the past year, in studying these issues and allowing for the accreditation of laboratories in these fields.

The Strict upholding of 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 2005 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 2005 ISRAC was examined by an international team on its work and professional competence. The results of the assessment were excellent, no non compliance was found in the fields of laboratory accreditation and inspection bodies, a result unparalleled in the world.

These results assure the Israeli regulators and the Israeli public of the high quality of the assessments and supervision preformed by ISRAC and that every effort is made to protect the public's interests and safety.

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 arena and on its devoted work and persistent efforts towards excellence.

Sincerely,
Prof. Mordechai Shani



The focus point of our activities during 2005 was the international evaluation that ISRAC underwent and which included all the existing types of accreditation.

The evaluation was performed by a team from the EA (European Accreditation), headed by Dr. Jeff Horlick from the U.S., who represented ILAC. The team was made of 5 delegates, each representing an accreditation field.

In preparation of the evaluation, which was held at the middle of the year, ISRAC laid down the infrastructure necessary for activities in all accreditation fields.

The preparations included scanning and updating all ISRAC procedures, training courses for ISRAC employees and assessors and holding a pilot program in each of the accreditation areas. During the preparations we learned that there is a need in the market for an Israeli accreditation body that will provide accreditation services in the fields of certification of personnel, quality management systems and assessment bodies. However, the domestic political situation did not allow the passing of a new law that enables ISRAC to broaden its scope of activities.

The international evaluation was a great success. No non-compliances were found in the fields of accreditation of laboratories and inspection bodies and in the new accreditation programs only one non-compliance was found owing to the fact the the procedure was not carried out fully. Therefore, if the law had been passed ISRAC would now be recognized internationally for all accreditation areas.

After the assessment, we devoted all our efforts to the negotiations with the Ministry of Law and Justice with the aid of the Ministry of Industry, Trade & Labor.

Significant advances in the understanding of the need of widening the scope of ISRAC activities were achieved during the negotiations and we hope that the law will be approved in the 17th Knesset, which is being sworn in at the moment.

ISRAC employees believe that our activities contribute an important part in raising the professional and normative levels of the work performed by laboratories in Israel. Therefore we continue to work with Laboratories, Regulators and Consumers.

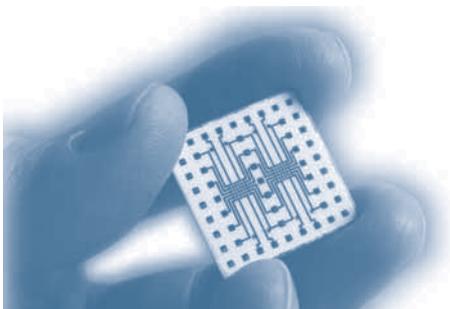
During the year we further deepened the cooperation with additional regulators. This cooperation gives the regulators a way of monitoring the activities performed in their field without imposing an additional burden on the governmental budget.

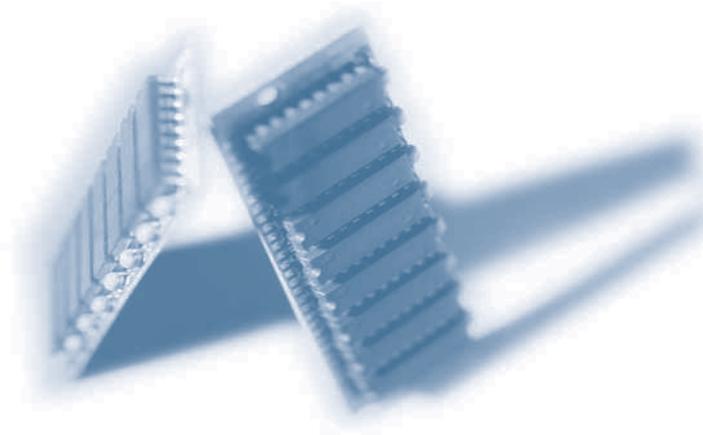
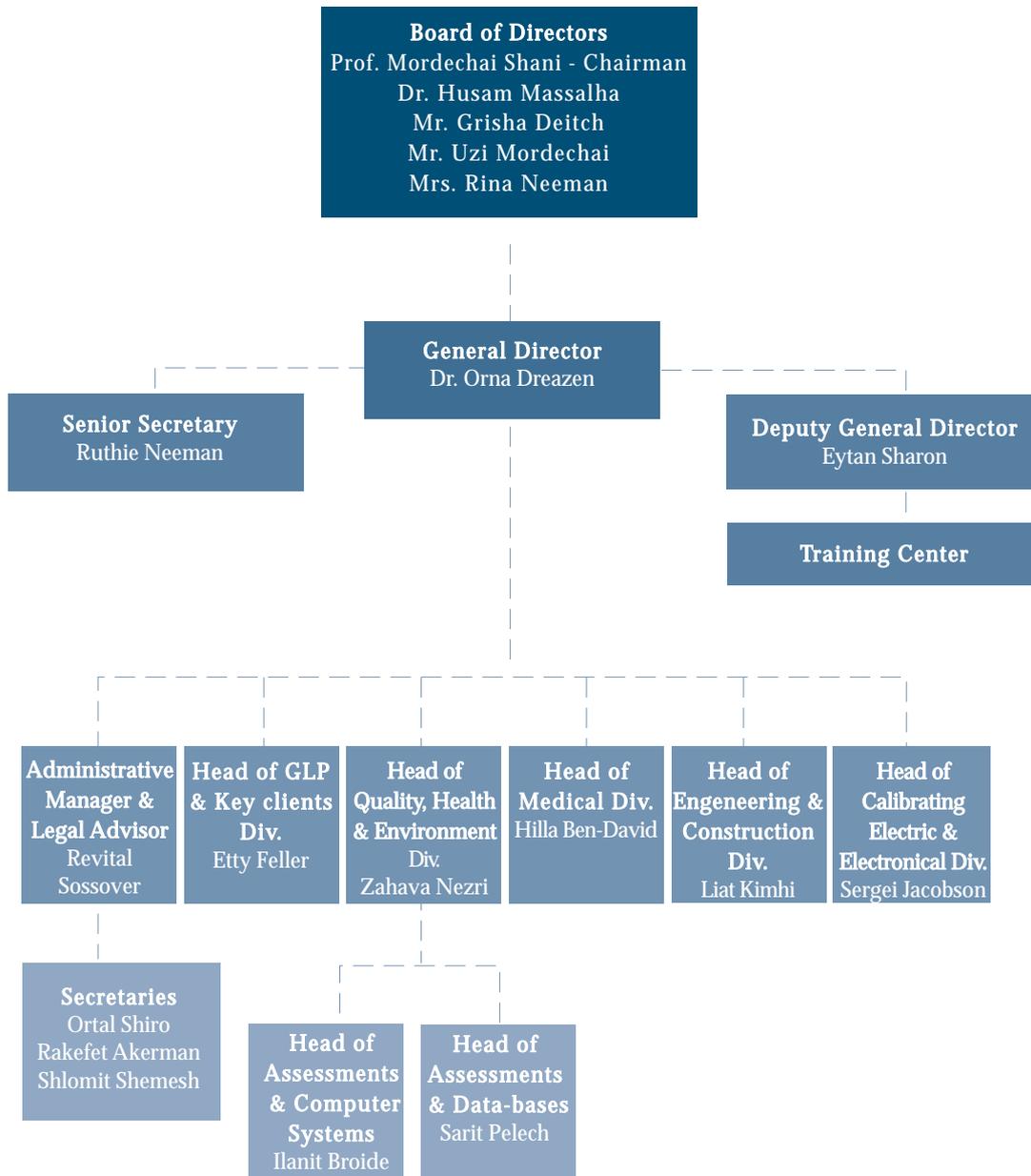
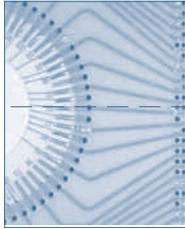
In addition, we hold many training activities at universities, for laboratory employees and consumers in order to deepen the awareness regarding the subject of measurement and the expertise of those who perform it, which form the basis for decision and policy making.

I would like to thank the various regulators, and especially the Ministry of Industry, Trade & labor, the stakeholders and our clients for their trust in our work.

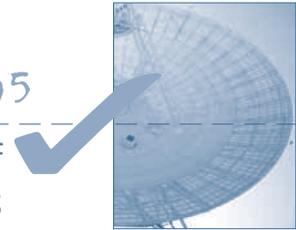
To all ISRAC employees, I would like to thank you for the growing effort you have invested in your work in spite of to the need for budgetary cuts.

Dr. Orna Dreazen





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.

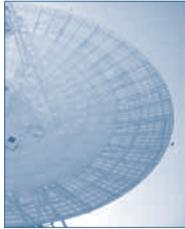
In 1992, in preparation for the establishment of an accreditation system in Israel, meeting international standards and gaining international recognition, the minister of industry and trade appointed a committee to examine the issue of the accreditation of laboratories.

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

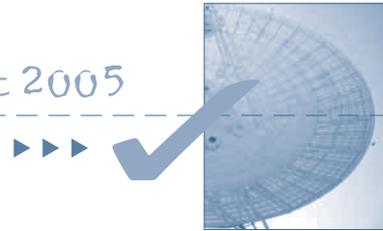
Laboratory accreditation may be provided for any type of properly documented test, measurement or calibration. At present, ISRAC accredits for the following types of tests / calibrations:

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.
- 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.

How to Contact ISRAC:

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Head of Engineering & Construction Div.	Liat Kimhi	B.Sc. Eng.	03-5751690(204)	liatk@israc.gov.il
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Central Areas of Activity during 2005



Last year we set ourselves the following goals:

- Changing the ISRAC law to include all types of accreditation.
- Broadening the scope of ISRAC's accreditation activities to include additional types of accreditation: Conformity assessment bodies, certification of management systems, certification of personnel, etc.
- Finish building the necessary infrastructure for performing assessments based on the rules of EFQM, in the public sector, in cooperation with the civil service unit.
- Finishing the establishment of the infrastructure necessary for the accreditation of certification bodies.
- Succeeding in the international evaluation in order to achieve international recognition for new fields of assessment and maintaining the current recognition in the field of laboratory accreditation.
- Supporting the Ministry of Trade, Labor & Industry in the task of designing and consolidation of the Standardization and conformity assessment activities.
- Passing a new ISRAC law.
- Broadening the cooperation between ISRAC and all regulators.
- Increasing the number of accredited organizations.

All goals that rely solely on ISRAC have been achieved. However, not all goals that depend on cooperation with others have been achieved.

Finishing the establishment of the infrastructure necessary for the accreditation of certification bodies.

In order to achieve this goal all the requirements for recognition published by the ILAC, IAF and EA were studied extensively.

The processes included training of the ISRAC employees and discussions on the optimal ways for implementing these requirements in ISRAC. During the studying process all ISRAC procedures and the ISRAC quality manual were updated accordingly. A special emphasis was put on avoiding any repeats in the procedures and rules as to avoid any contradictions between them.

The process was completed during the first trimester of the year and all ISRAC procedures were submitted to the evaluation team, which carried out the evaluation during June.

The assessment team went through the procedures and found them in compliance with the work of an accreditation body.

Success in the international evaluation

During the month of June an international team of evaluators arrived, on behalf of the EA and ILAC, in order to assess the activities of ISRAC in the field of laboratories including medical laboratories, and in all other fields of accreditation. The evaluation included discussions and interviewing of all ISRAC personnel regarding their mode of operation in different situations, review of the existing documentation regarding the accreditation of different organizations and internal quality activities, including: Handling of complaints, management review, internal assessments, review of PT activities of laboratories and other issues regarding the implementation of ISO/IEC 17011 and the requirements of international accreditation organizations.

In addition, the assessors took part for three days in assessments conducted by ISRAC assessors. Emphasis was given to assessors who were not viewed in the last international evaluation and new fields of accreditation such as medical laboratory accreditation.

A big effort was put into a thorough analysis and exposure of the work performed by ISRAC. The evaluators did not find any non-conformity in the fields of laboratory accreditation and the accreditation of inspection bodies.

However, one non-conformity was found in the field of certification, which resulted from the fact that ISRAC is not permitted to complete the procedure of accreditation of certification bodies by law. The international assessment team recommended the extension of the international recognition of ISRAC in the field of laboratory accreditation, including medical laboratories, and expand the recognition to the field of inspection bodies immediately. Regarding certification bodies it was agreed that a limited assessment will be performed after the extension of the ISRAC law in order to ensure the system is working accordingly.



Consolidation and design of the Standardization and conformity assessment activities in the Ministry of Trade, Labor & Industry

The activities of the Ministry of Trade, Labor & Industry are divided into several areas and ISRAC is active in the following two: Standardization and conformity assessment activities and International Trade activities.

ISRAC representatives take an active part in the consolidation and redesigning of the standardization and conformity assessment activities.

The Ministry of Trade, Labor & Industry has assigned itself several goals on the subject:

- Organizing and strengthening the regulation.
- Avoiding non-conformities and overlap between the different bodies of the Ministry.
- Review of the subjects in which the government should be involved.

These activities allow for better understanding between the different bodies that are active in this area and the resolution of controversial issues. The results of this activity are better cooperation between ISRAC, the commission of standards and the department of legal metrology.

Passing ISRAC law

The work on this goal is still in progress. The political reality did not make it possible to pass the law last year. However, a breakthrough was achieved at the end of 2005 after the Ministry published a document detailing all the regulators in the Ministry of Trade Commerce and Labor that need a second authority to cosign their regulation.

The legal department prepared a list of laws that the Ministry is in charge of enforcing and in which it can use the professional capacities of ISRAC to ensure the public's well-being and safety.

The document showed in detail how each regulator can use the services of ISRAC and the legal basis that supports it. The ministry of Justice held a discussion, headed by Mrs. Didi Lachman-meser, in which it was agreed that the Ministry supports the legislation of a law defining an accreditation authority that will assist the regulators of the Ministry of Trade, Labor & Industry. It was also agreed that an expansion to the law shall be considered in order to allow other governmental offices to use the services of ISRAC. We are at the moment working on the wording of these agreements in order to present them before the present Knesset.

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 hygienic employment and we are working on additional fields such as noise level testing.

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	From June 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 2006



- 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 2005

Budget for 2005 and 2006



Budget for 2005 and 2006

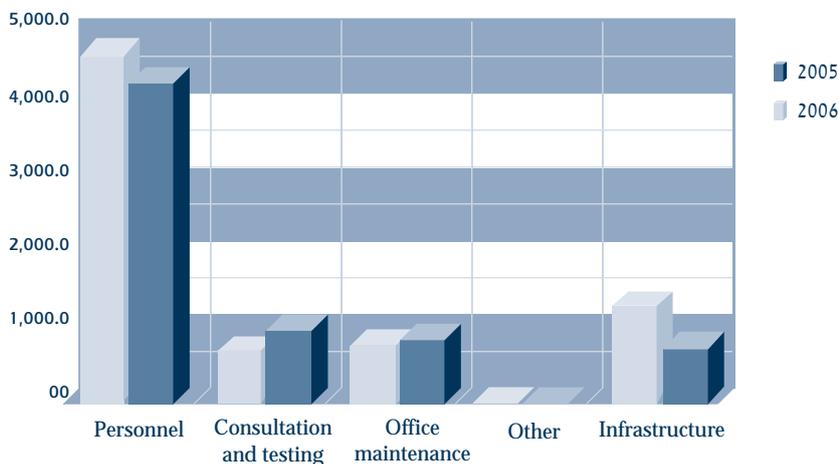
	2005 budget	2006 budget	Nominal Change
	NIS 000's	NIS 000's	%
Expenditure			
Regular operations	3,944.6	3,844.7	-2.5
Development	3,441.4	3,699.3	7.5
Total Expenditure	7,386.0	7,544.0	2.1
Income from Operations			
Accreditation and surveillance	3,167.0	2,520.0	-20.4
Training and GLP inspections	245.0	360.0	46.9
Total Income from Operations	3,412.0	2,880.0	-15.6
Income from Funding			
Funding of development - State budget	3,441.4	3,699.3	7.5
Regular funding - State budget	532.6	964.7	81.1
Total Income from Funding	3,974.0	4,664.0	17.4
Total Income	7,386.0	7,544.0	2.1

Expenditure

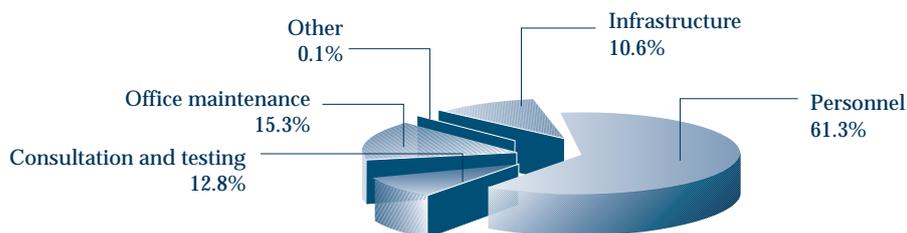
		2005	2006 budget	Nominal Change
		NIS 000's	NIS 000's	%
Expenditure				
1.0	Personnel	4,304.0	4,577.0	6.3
2.0	Consultation and testing	1,071.5	843.0	-21.3
3.0	Office maintenance	900.0	830.0	-7.8
4.0	Other	5.0	5.0	0.0
	Total operating expenditure	6,280.5	6,255.0	-0.4
	Development element	-2,335.9	-2,410.3	3.2
	Total regular operations	3,944.6	3,844.7	-2.5
5.0	Infrastructure	1,105.5	1,289.0	16.6
	Development components	2,335.9	2,410.3	3.2
	Total development	3,441.4	3,699.3	7.5
	Total	7,386.0	7,544.0	2.1



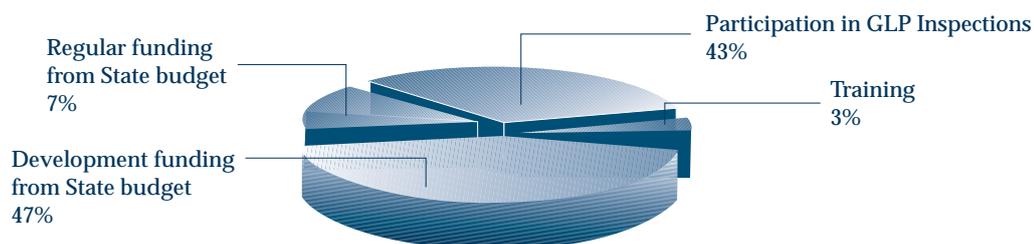
Forecast of Expenditure in the 2006 Budget in Comparison with the 2005 Budget:



Breakdown of Expenditure in 2005



Breakdown of Income in 2005

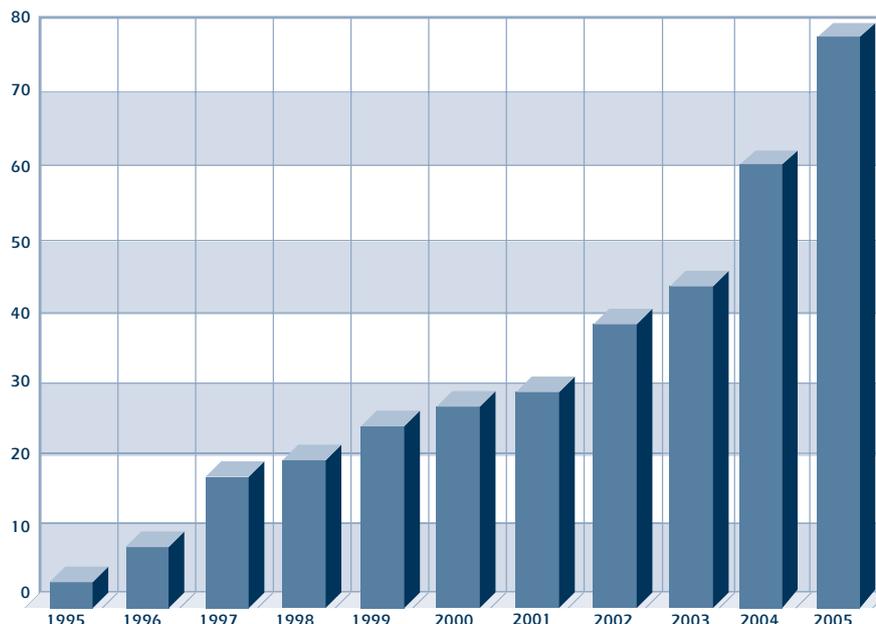


As of January 2006, 73 laboratories have received accreditation, and 7 research facilities received recognition to GLP. 16 laboratories are in the process of accreditation and 1 research facility is in the process of recognition for GLP.

Department	No. of accredited labs.	No. of labs. In the process of accreditation
Engineering	21	4
Biology & Chemistry	21	3
Medical	13	6
Calibration	5	0
GLP	15	3
	7	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.