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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 two years, in studying these issues and building and improving the infrastructure for accreditation of laboratories in these fields.

The Strict upholding of standards in all its areas of work is one of the central obligations 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 intension to broaden the number of accredited laboratories in Israel in many different fields.

During the year 2004 ISRAC 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 during the year 2005.

As part of its international activities ISRAC has been appointed as the state of Israel's representative in the environmental committee at the OECD.

ISRAC had undergone assessment by a team from the OECD in order to become a full-fledged member of the committee. The assessment was very successful and following it Israel was accepted as a full-fledged member in this committee.

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 their devoted work and persistent efforts towards excellence.

Sincerely,
Prof. Mordechai Shani



The year 2004 served as a turning point in the situation of the Israel Laboratory Accreditation Authority. We see ourselves as an important and vital part in the campaign for raising the awareness and quality of conformity assessment services in Israel. In order to achieve that goal we hold comprehensive introductory and training activities, including all stakeholders: Laboratories, Regulators, Industry, Chambers of commerce, etc.

The many activities we hold and the support of the Ministry of Industry, Commerce and Employment have succeeded in deepening the awareness to our activities and goals.

The raising awareness on one side and many problems and incidents encountered by the different regulators, on the other have brought most of the regulators that use conformity assessment to employ the services of ISRAC.

The Ministry of Industry, Commerce and Employment has held several serious discussions regarding the field of conformity assessment in which ISRAC played an active part.

A number of breakthrough decisions have been reached regarding the broadening of the accreditation scope of ISRAC to include all certification bodies.

This shall allow ISRAC to assess all types of systems, whether they have so far been accredited by foreign bodies or have not been supervised before.

We believe that broadening the scope of accreditation and its execution by a national, Hebrew-speaking, body that is familiar with the Israeli market, shall improve the quality and aid the industry in the process of marketing its products abroad.

A proposal for changing the ISRAC law was submitted in 2004.

ISRAC employees have been preparing the infrastructure needed for working on additional accreditation fields. In order to achieve international recognition in these additional fields ISRAC shall undergo an evaluation by EA and ILAC at the middle of 2005.

During 2004 we have deepened our international involvement in ILAC, European market and OECD activities. ISRAEL was accepted as a full member in the OECD-GLP Committee, which is a sub-committee of the Committee on Chemistry and the Environment.

In addition, I was elected as chairman of the ILAC committee dealing with arrangements between ILAC members and many other international organizations and which determines the rules for the conduct of ILAC members.

These activities bring Israel in contact with all the leading economic organizations in the world and also with the international standardization organization.

We hope to deepen our involvement in the international market and our cooperation with the industry, exporters and different laboratory clients in the future, in order to better understand their needs and help them receive the service that suits them.

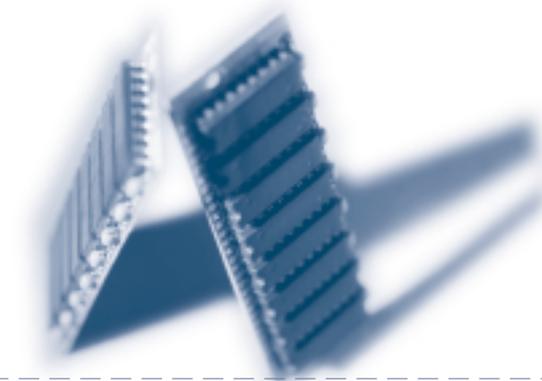
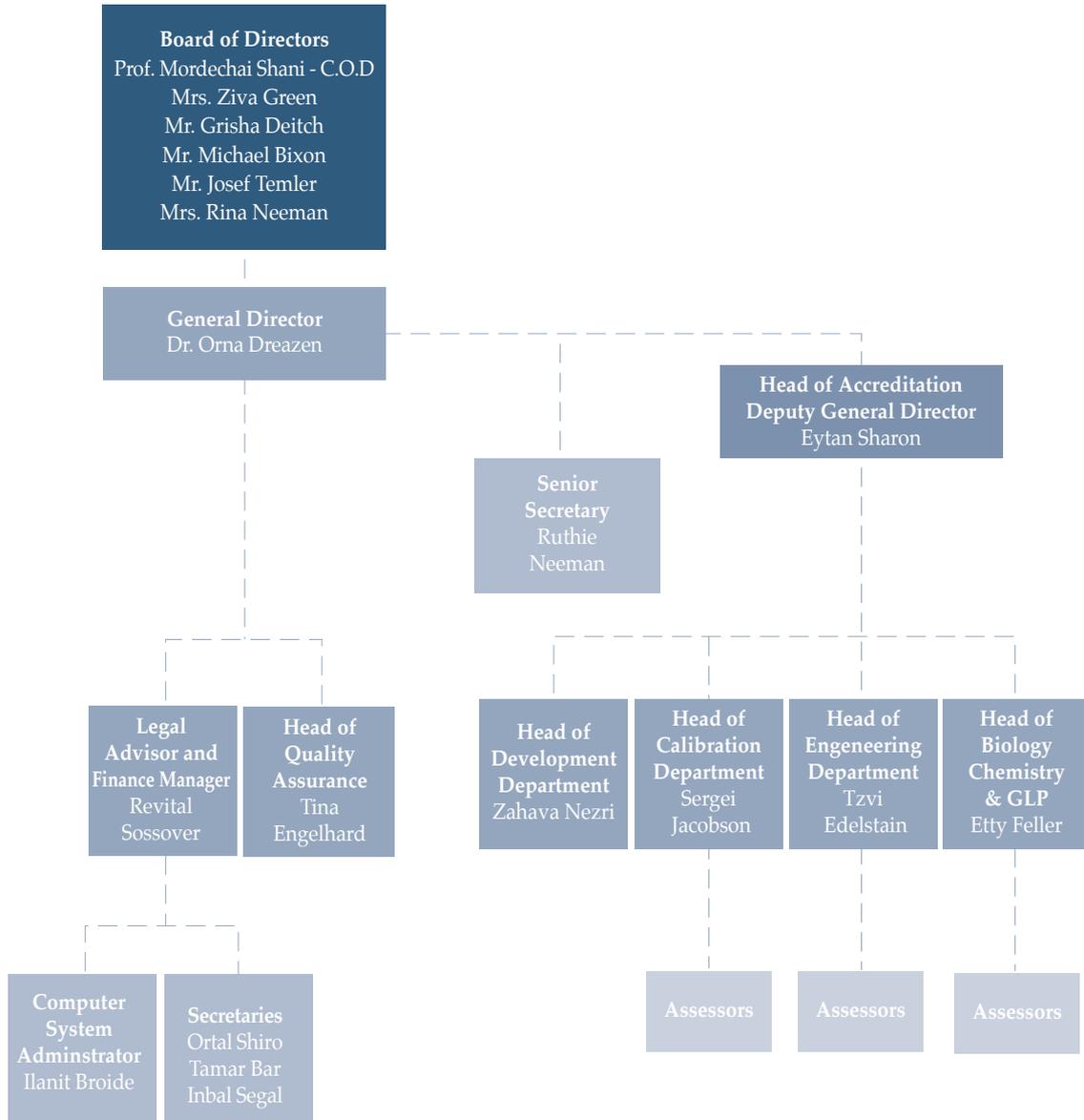
I would like to thank the different regulators, and especially the Ministry of Industry, Commerce and Employment, the stakeholders and our clients for their trust in our work.

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

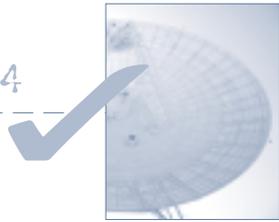
Dr. Orna Dreazen



Organization chart



About ISRAC and ways of
establishing contractual relations



The early 1990s saw 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 proper 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



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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 are based on the international standard ISO/IEC 17025-1999: "General requirements for the competence for testing and calibration laboratories." Medical laboratories are accredited according to a specific standard, ISO 15189, which is based on the ISO/IEC 17025. In addition, specific criteria for various fields complete the general criteria.

In practical terms, ISRAC ascertains the following in accrediting a laboratory:

- Laboratory facilities, professional capability and systems are appropriate for performing the tests and calibrations listed in the scope of accreditation.
- The quality system of the laboratory meets all requirements of the relevant standard ISO/IEC 17025 (1999) or ISO 15189 and thereby sections of ISO 9001 (1994), ISO 9002 (1994) - and is properly documented and fully implemented.
- The laboratory meets ISRAC's complementary criteria for the accreditation of laboratories in areas relating to its scope of accreditation, relating primarily to requirements in the Israeli law or reality, or constituting an extension or explanation of generalized statements in the standard.

Accreditation for a laboratory is not generalized, but granted for specific methods of testing and calibration, as detailed on ISRAC's Internet site, www.israc.gov.il.

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:

Address for letters: 2 Habonim st. Beit Habonim Ramat Gan, Israel.

Telephone: 03-5751690, **Fax:** 03-5751695, **E-mail:** israc@israc.gov.il, **Web Site:** www.israc.gov.il

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The following goals were set by ISRAC for the year 2004:

- Increasing the number of Accredited Laboratories.
- Striving to sign agreements between Israel and other countries, based on accreditation, for the benefit of the industry.
- Joining the OECD-GLP committee, after evaluation.
- Expanding the international connections of ISRAC.
- 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.
- Building the necessary infrastructure for performing assessments based on the rules of EFQM, in the public sector, in cooperation with the civil service unit.

Most of the goals have been achieved!

Increasing our clientele

During the year 2004, 10 more laboratories received accreditation.

The new laboratories are in the fields of NDT, engineering, metrology, calibration, sampling, chemistry and medical laboratories.

In addition, 20 laboratories are currently in the process of accreditation and two of them received accreditation during 2005.

ISRAC also works on maintaining and cultivating its clientele through direct contact, complaint handling, surveillance of their activities, development of guidance documents, training and more.

Agreements between Israel and other countries

Despite the tremendous efforts that were invested in writing and presenting draft agreements to different countries in different fields, no agreements have been signed during 2004. In most cases the Israeli regulators allow the entrance of international

merchandise, without further tests or inquiries. Therefore, signing an agreement between Israel and another country shall give the Israeli manufacturers an advantage and shall negatively affect the manufacturers in the target country by raising their competition. On the other hand, even without an agreement these manufacturers don't meet with any problems in exporting their merchandise to Israel today, therefore signing an agreement does not offer them any advantages. That is why the American Ministry of trade and Industry objected to signing an agreement with the Israeli Ministry of Communications and the Ministry of Industry, Commerce and Labor despite the fact that the American Ministry of Communications agreed to sign a mutual recognition agreement (MRA).

In addition, a draft of an MRA agreement was submitted to the Singapore Ministry of Trade and Industry, and it is under negotiation.

Striving to sign agreements between Israel and other countries, based on accreditation, for the benefit of the industry

ISRAC cooperates with the Export Institute, the manufacturers association of Israel and the bureau of commerce, in this field.

Two important meetings were held with the industry, together with the export institute, during the year 2004:

- A meeting with the OECD staff, headed by Mr. Jim McCormack, head of the GLP program in the FDA. About 50 representatives from the Israeli industry participated in this meeting, and they learned there from the American, Dutch and Canadian representatives how much the Israeli accreditation program for recognition of research facilities is valued around the world.

- Another meeting was held between the former head of ILAC, Mr. Mike Peet and the representatives of the industry. This meeting was organized with the support of the Export Institute and the Ministry of Industry, Commerce and Labor. In the meeting, the deputy general director of the Ministry of Industry, Commerce and Labor, Mr. Udi Shental, presented the ministry's view regarding the field



of standardization. Mr. Peet presented the globalization process of the international market and the benefits that ILAC activities hold for exporters.

- ISIRAC has participated in many expositions and conferences organized by the industry, such as the national conference of the food industry that was organized by the manufacturers association of Israel, the Telecom exposition, the Ministry of Environment's conference and a virtual exposition on agriculture.

Joining the OECD-GLP committee

During the year 2004 ISIRAC underwent an evaluation of its system for recognition of research facilities working in compliance with GLP rules. The evaluation team included the heads of the recognition program from Canada, the Netherlands and the FDA in the United States.

The team received full cooperation from ISIRAC, the relevant regulators, the Ministry of Finance that is in charge of the acceptance of Israel to the OECD and the facilities that had to undergo assessment under the surveillance of the team. We deeply thank all those that took part in the evaluation.

As a result of the evaluation, the team filed a report recommending the acceptance of Israel as a full member in the GLP committee.

After reviewing the report the committee voted unanimously on the acceptance of Israel. The decision was passed to the Environmental committee and the vote was again unanimous for Israel. The Minister of Industry, Commerce and Labor was invited to agree to the conditions for joining the committee and appoint a representative to it.

At the beginning of 2005, the secretary of the OECD published an official announcement regarding the acceptance of Israel as a full member in the GLP committee. ISIRAC is represented in the committee by Mrs. Ety Feller, head of the GLP program in ISIRAC.

The Minister of Industry, Commerce and Labor sees this step as an important step for Israel in the process of being accepted as a full member in the OECD.

Expanding the international connections of ISIRAC

ISIRAC is working on expanding its international connections with economic organizations, standardization organizations (especially ISO) and technical organizations that grant valuable recognition to Israeli laboratories.

Therefore ISIRAC representatives have broadened their international activity in all fields.

Connections with technical organizations:

- ISIRAC has performed assessments in the industry following the request of General Electrics, a firm working with the Israeli industry.
- Joint assessments were performed with ISTA, the international seed association.
- Joint assessments were performed with EFI (European Federation for Immunogenetics), an organization that deals with laboratories in the field of Genetics. Joint assessments save the labs unnecessary expenses and enable them to gain national and international recognition in the most efficient manner available.

Connections with standardization organizations

In the past year, ISIRAC's General Director has been in charge of following-up on all the relevant committees in ISO/CASCO, for ILAC. As part of the follow-up we have read and responded to many standard proposals and have succeeded in greatly influencing the standardization process in many committees. This activity has greatly strengthened the ties between ILAC and the ISO/CASCO organization, leading to the signing of an MRA between the two organizations. In order to solve problems together, our General Director participates in a joint committee to ILAC, ISO and IAF.

Additional International Activities

- ISIRAC's General Director has been appointed to head the ILAC MRA committee. This committee deals with many subjects, including:
 - Activities with customer and economic organizations.
 - Conditions for recognition between accreditation bodies.
 - Working with regulators worldwide.



- In addition, ISRAC employees participate in the following committees:
 - ILAC committee for defining the rules for accreditation.
 - EA committee for defining the rules for accreditation.
 - EA General assembly.
 - The OECD-GLP committee.
- A lot of work has been invested as part of the preparations of the European market for working with middle eastern countries. Representatives of ISRAC participated in two conventions together with representatives from the Minister of Industry, Commerce and Labor and the Israeli institute of standards.

Providing training in areas regarding the fields of metrology and laboratory quality

ISRAC organizes many courses in the fields of metrology and laboratory quality in the following formats:

- ISRAC courses, a list of which is published in the ISRAC website and newsletter.

- A full course in metrology at the Weizmann institute of science.
- Lectures at different faculties as part of existing courses in all the Israeli universities.
- Instruction and courses in big organizations and enterprises that are interested in extending their employees' knowledge.

Changing the ISRAC law

During 2004 a new draft for the law was written at the Ministry of Industry, Commerce and Labor defining ISRAC as a body dealing with the accreditation of all types of certification bodies. At the same time ISRAC has established the infrastructure necessary for the new activities defined by the law.

EFQM

ISRAC has begun cooperating with the department for quality and excellence in the civil service unit, in order to build a program for holding assessments regarding the compliance with EFQM rules in the public service.



The main activities planned for the year 2005



- To finish establishing the infrastructure for the accreditation of certification bodies.
- Succeeding in the international evaluation in order to receive international recognition in new fields and maintain the existing recognition in the field of laboratory accreditation.
- Aiding the Minister of Industry, Commerce and Labor in defining and modeling the field of standardization.
- Passing the new ISRAC law.
- Expand the work with regulators.
- Increasing the number of accredited organizations.



Annual Report 2004

Budget for 2004 and 2005

Budget for 2004 and 2005

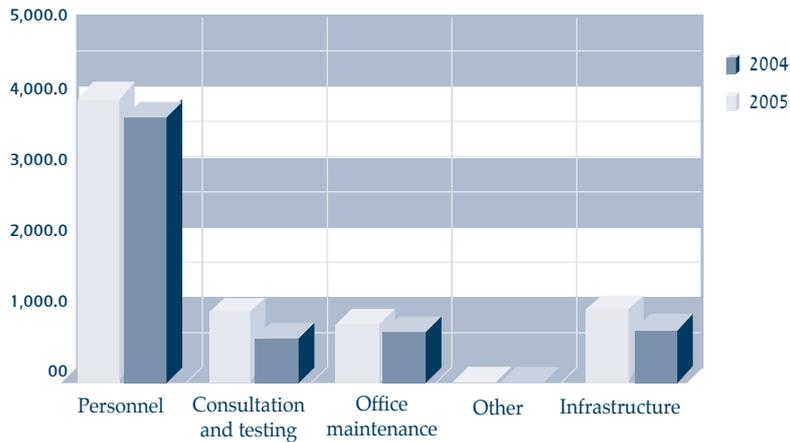
	2004 budget	2005 budget	Nominal Change
	NIS 000's	NIS 000's	%
Expenditure			
Regular operations	3,304.0	3,944.6	19.4
Development	2,926.0	3,441.4	17.6
Total Expenditure	6,230.0	7,386.0	18.6
Income from Operations			
Accreditation and surveillance	1,960.0	3,167.0	61.6
Training and GLP inspections	270.0	245.0	-9.3
Total Income from Operations	2,230.0	3,412.0	53
Income from Funding			
Funding of development - State budget	2,926.0	3,441.4	17.6
Regular funding - State budget	1,074.0	532.6	-50.4
Total Income from Funding	4,000.0	3,974.0	-0.7
Total Income	6,230.0	7,386.0	18.6

Expenditure

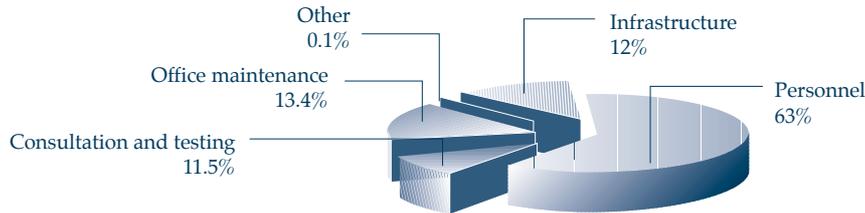
		2004 budget	2005 budget	Nominal Change
		NIS 000's	NIS 000's	%
Expenditure				
1.0	Personnel	3,927.4	4,304.0	9.6
2.0	Consultation and testing	717.9	1,071.5	49.3
3.0	Office maintenance	834.0	900.0	7.9
4.0	Other	5.0	5.0	0.0
	Total operating expenditure	5,484.3	6,280.5	14.5
	Development element	-2,180.3	-2,335.9	7.1
	Total regular operations	3,304.0	3,944.6	19.4
5.0	Infrastructure	745.7	1,105.5	48.2
	Development components	2,180.3	2,335.9	7.1
	Total development	2,926.0	3,441.4	17.6
	Total	6,230.0	7,386.0	18.6



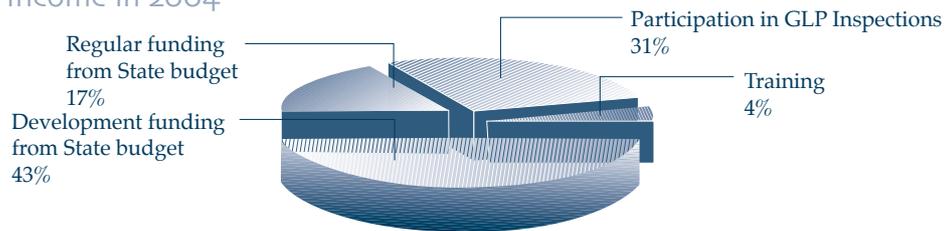
Forecast of Expenditure in the 2005 Budget in Comparison with the 2004 Budget:



Breakdown of Expenditure in 2004



Breakdown of Income in 2004

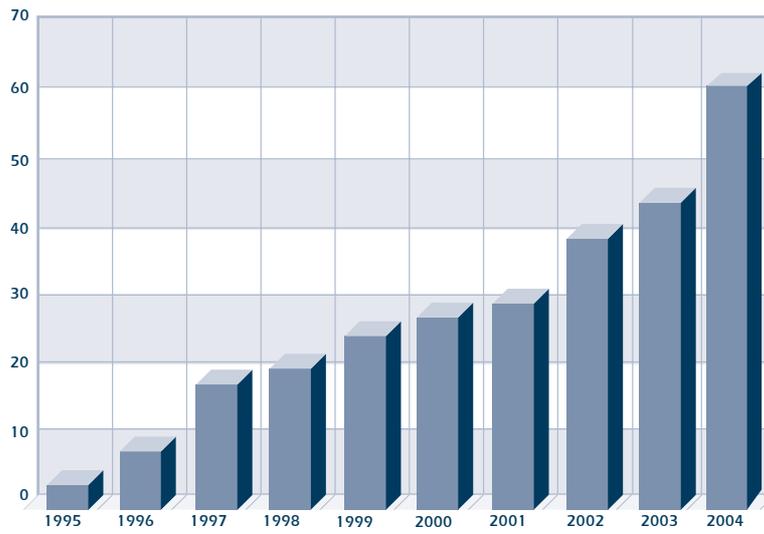


As of January 2005, 58 laboratories have received accreditation, and 6 research facilities received recognition to GLP. 20 laboratories are in the process of accreditation and 1 research facility is in the process of recognition for GLP.

Department	No. of accredited labs.	No. of labs. In the process of accreditation
Engeneering	17	8
Biology & Chemistry	25	8
Medical	12	3
Calibration	6	1
GLP	4	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)



Can do so through the ISRAC web site (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.