



Ministry of Industry, Trade & Labor



ISRAC

Israel Laboratory Accreditation Authority



Annual Report

Year
2003





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Dear friends,

The Israel Laboratory Accreditation Authority (ISRAC) was established in 1997 as a national infrastructure for the benefit of the Israeli people. Among ISRAC's customers are daily users of its laboratory testing and measurement services, as well as industries producing for local and export markets. A distinctive feature of any modern state is its primary obligation to adhere to the highest standards of activity. The first principle of upholding standards is proper training of the testing bodies and their adjustment to international standards and local needs. This is the task of the Israel Laboratory Accreditation Authority, which intends to widen the circle of accredited laboratories active in many different fields. During 2003 there has been significant strengthening of cooperation between ISRAC and many of the regulators. Many public laboratories have either initiated the process for preparing for accreditation or have been accredited.

This activity ensures that the citizen of the state of Israel can now make decisions based on valid data. In 2003 the Ministry of Trade and Commerce have redefined the standardization infrastructure. ISRAC management has taken an active role in these discussions. In this framework ISRAC is preparing to expand its responsibilities of accreditation to all types of conformity assessment bodies. We hope that the implementation of this change will be effective through the update of the Israel law during the year 2004.

Within the international activities ISRAC has been nominated as the official representative of Israel as an observer at the committees of the Environment at the OECD.

ISRAC has prepared itself for a mutual joint visit team from the OECD in order to become a full member on this committee. This will be the first membership of Israel on a OECD committee.

I hope that this would be the first step for accepting Israel as a member in this important economic organization.

I wish the accredited laboratories continuous success and improvement. Those who embark on the long journey of the accreditation procedure I can assure that with perseverance and single-mindedness you will achieve the desired goal.

I congratulate ISRAC's staff on its international accomplishments and dedication to its job, while aiming continuously at standards of excellence.

Sincerely,
Prof. Mordechai Shani



Year 2003 was a turning point in the positioning of ISRAC.

We now see ourselves as a vital and essential part in promoting the awareness and the quality of the test services in Israel. For this reason we have established comprehensive explanatory documents and training sessions in cooperation with interested parties such as: laboratories, regulators, industry and commerce.

Many of activities that ISRAC has performed together with the support of the Ministry of Trade, Industry and Labor enabled ISRAC to strengthen the awareness of its existence and the trend that we are leading. This exposure on one hand and the resolutions of problems on the other has brought many regulators to an understanding that part of their work depend on the test results and they could benefit from utilizing ISRAC services.

Intensive discussions were held in the Ministry of Industry, Trade and Labor. Two such discussions were on the structure and responsibilities regarding the overall standardization infrastructure of Israel. Members of ISRAC have been active members to these discussions. One of the decisions related to the authority of ISRAC was that ISRAC could accredit all types of certifications. ISRAC Law will be amended to allow accreditation of all sorts of systems, those that have been accredited, up to now, by international bodies and those that have not been accredited internationally.

We believe that the extension of accreditation and its implementation by an Israeli body, speaking Hebrew, and with the knowledge of the local market will benefit the quality and assist the industry to market its products overseas.

Based on the future plans the ISRAC law should be changed in 2004, which will allow us to apply for international recognition during the year 2005 for the extended activities.

In 2003 ISRAC implemented a new pricing and surveillance system. Based on this system ISRAC charges its accredited laboratories a fixed price according to the amount of technologies defined in the scope of each accredited laboratory. This method enables transparency, possibility to organize finances of the lab and encourages them to receive accreditation for all types of tests within the same technology without any extra expense.

As any process, this process has opened many questions and mis-understandings, even though for most of the labs this has usually lead to a cut in expenses for the overall accreditation. After a year of implementation we believe that this change has been for the better, for ISRAC for the regulators and for Laboratories' customers. In comparison to prices internationally, in most cases, ISRAC prices are less expensive.

In 2003 ISRAC has extended its international activities in ILAC and in the European Union and OECD. Within this framework of activity we have promoted the preparation of an international agreement between Israel and the American Ministry of Communications (FCC). In addition we work in collaboration of the Ministry to prepare such an agreement with Singapore. We hope that such an agreement maybe signed during 2004.

In the future we aim to intensify our involvement in the market and our cooperation with the industry and exporters, customers of the laboratories in order to improve and understand their requirements and assist them in receiving the desired service.

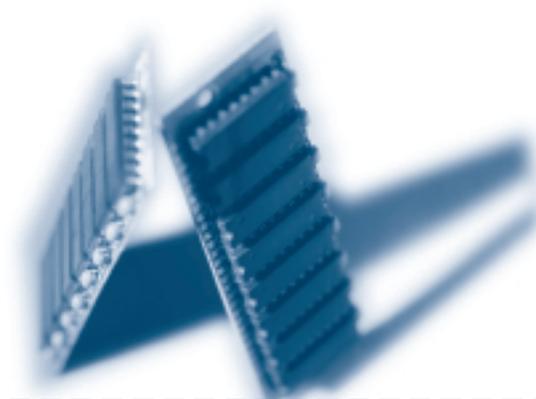
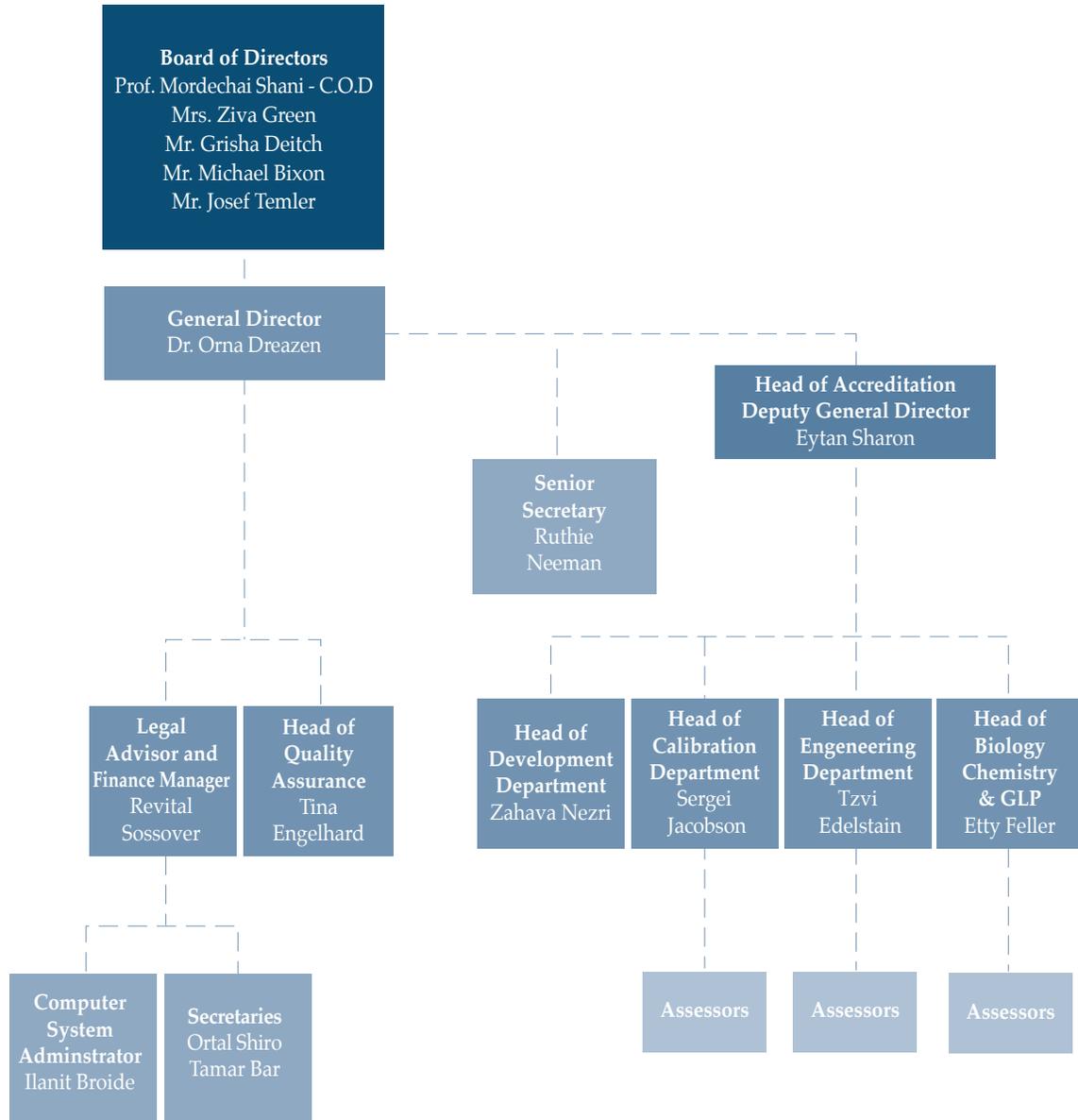
I would like to thank the different regulators, first and foremost the ministry of Industry, Trade and Labor, stakeholders, and our customers for having faith in ISRAC.

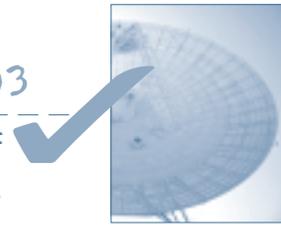
To the staff of ISRAC a warm thank-you for the increased efforts required to achieve our goals even though the funding was reduced.

Dr. Orna Dreazen



Organization chart ✓





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 to 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 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 ancillary 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 sector or the 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 enabling clients and major consumers in the economy, such as the enforcement authorities, to assure that they acquire 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 has been 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 in 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 in 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 proper code of conduct - objectivity, transparency and avoiding conflicts 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 a definition of the 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 Accredited Laboratory

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 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 in order to perform the tests and calibrations listed in the scope of accreditation.
- The quality system of the laboratory meets all components 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 Israeli law or reality, or constituting an extension or explanation of generalized statements in the standard.

Accreditation for a laboratory is not generalized, but is 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.



The Added Value for the Accredited Laboratory

An accredited laboratory is permitted to mention its accreditation in its documents and in 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 32 countries including Western European nations, United States, Japan, Australia, India, China and additional countries around the world.

The quality system provides a tool ensuring that the laboratory will monitor its activities and draw conclusions in order to ensure constant improvement. Accreditation is recognized by the European governmental authorities and, in many cases, provides a basis for their recognition. Laboratories that function in accordance with the rules of accreditation improve the efficiency of work processes, including: proper first-time implementation, reducing the number of repeat testing; preventative maintenance of equipment, saving unnecessary investments in repairs and acquisitions, and so on.

How to Contact ISRAC:

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Last year ISRAC had the following goals

- Strengthen the awareness of the activities of ISRAC among the regulators and the users in the laboratory services.
- Develop new accreditation areas such as: electrical tests, electronic signature and more.
- Provide knowledge and training related to the management of quality in the laboratories.
- Prepare a computer system for managing and monitoring the assessment and surveillance activities.
- Implement a new surveillance method.
- Implement and review of a new pricing system.
- Broaden our accreditation of medical laboratories.
- Broaden our international contacts.
- Prepare and present training and seminars in the area of accreditation and recognition to GLP.

Most of these goals were achieved.

ISRAC for the regulators

In order to strengthen the awareness of ISRAC activities amongst the regulator the following activities were performed:

- Explanatory meetings.
- Resolution of professional problems presented by the regulators in order that they gain confidence in the technical competence of ISRAC.
- Resolution of legal problems while working with non-accredited laboratories.
- Promotion of an understanding of the tool that ISRAC has to offer to its regulators.
- Promotion of an understanding that ISRAC works with the regulators rather than against them.

In 2003 some of the regulators published requirements for their recognized laboratories. These included that, within a defined timescale the labs would be obliged to be accredited. The regulators that have made this decision are:

- Ministry of Defence: The supplies section for the army has stated that it receives tenders only from accredited laboratories.

- Agriculture: for pesticide residues testing, only accredited labs are accepted.
- Environment: Dust, Chimnies and fuel leakage testing.
- Justice: Electronic Signature.
- Industry, Trade & Commerce: occupational health.
- Internal affairs: Sprinklers and fire extinguisher systems.
- Health: Public health laboratories (water, food and pesticides) and medical laboratories.

Development

The activities that were under development for year 2003 split between the development of the infrastructure and new accreditation areas. Within the development of the infrastructure, a project of improving and harmonizing the scopes of accreditation for the field of engineering, chemistry and biology was implemented. The revision and upgrading of the calibration certificates should be completed by 2004.

A requirements document for computerized systems has been prepared for laboratories and test facilities and training on this document is planned for 2004.

A national project for writing procedures in the medical laboratories has been initiated and example procedures are now available for:

- Biochemistry
- Blood Bank
- Microbiology
- Fertility

The procedures are on the ISRAC web: www.israc.gov.il. It is our hope that this will assist laboratories to summarize the tests performed as documented procedures. Additional procedures in different medical areas will be written and added to the website.

Within the new accreditation areas the following activities have been finished:

- Piles and Sonic and Ultrasonic tests.
- Boilers

Activities, which will continue into 2004:

- Electronic Signature



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- Water meters calibration labs
- Electrical testing
- Medical laboratories

As part of a marketing program, the medical laboratories were offered to join a pilot program for accreditation of their laboratories. This project opened a channel of communication which helped ISRAC to understand the special cases and

unique problems in the field of medical laboratories. Five organizations joined the project of which 2 decided not to continue and one wished to wait a while. One is now before being granting accreditation and the two hospitals of Hadassah in Jerusalem (Har- Hazofim and Ein Kerem) have received accreditation to part of the overall laboratory division.



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Main Activities Planned for 2004



- Increase the number of accredited laboratories.
- Promote agreements between Israel and other countries based on the accreditation for the benefit of the industry.
- Strengthen the ties and the cooperation with the industry.
- Join and participate the OECD-GLP – Working group.
- Strengthen the international ties with ISRAC.
- Broaden the knowledge and the training in areas with such as Metrology and Quality in the laboratories.
- Change ISRAC law in order to include other types of accreditation.
- Expand the activities of ISRAC to additional accreditations of inspection bodies, certification and management systems, and certification of personnel.
- Build an infrastructure for assessments in the public sector based on the guidelines of EFQM together with the Civil Services Government.



Budget for 2003 and 2004

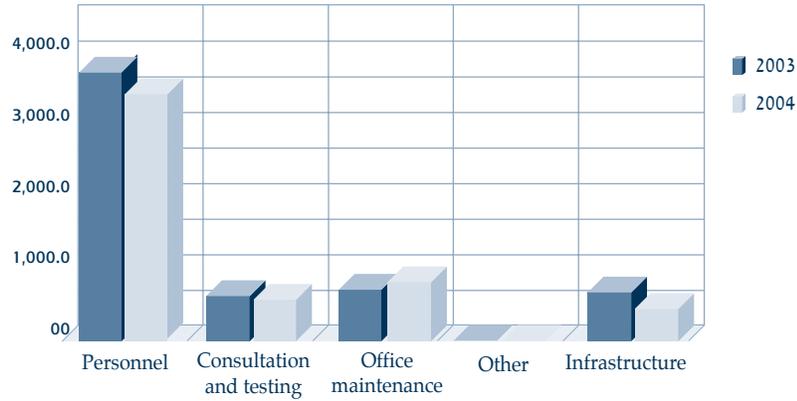
	2003 budget	2004 budget	Nominal Change
	NIS 000's	NIS 000's	%
Expenditure			
Regular operations	2,691	2,355.3	-12.5
Development	2,961	2,878.7	-2.8
Total Expenditure	5,652	5,234	-7.4
Income from Operations			
Accreditation and surveillance	1,495	1,909	27.7
Training and GLP inspections	270	270	0.0
Total Income from Operations	1,765	2,179	23.5
Income from Funding			
Funding of development - State budget	2,961	2,878.7	-2.8
Regular funding - State budget	926	176.3	-81.0
Total Income from Funding	3,887	3,055	-21.4
Total Income	5,652	5,234	-7.4

Expenditure

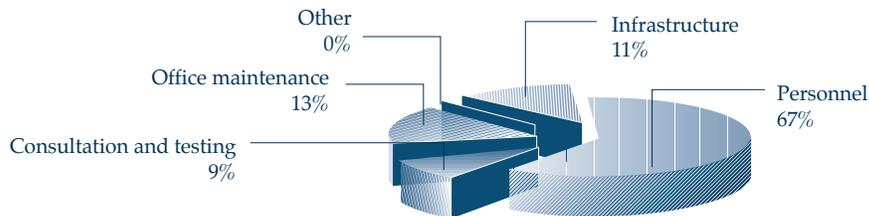
		2003 budget	2004 budget	Nominal Change
		NIS 000's	NIS 000's	%
Expenditure				
1.0	Personnel	3,729	3,488	-6.5
2.0	Consultation and testing	530	521	-1.7
3.0	Office maintenance	753	834	10.8
4.0	Other	5	5	0.0
	Total operating expenditure	5,017	4,848	-3.4
	Development element	2,326	2,492.7	7.2
	Total regular operations	2,691	2,355.3	-12.5
5.0	Infrastructure	635	386	-39.2
	Development components	2,326	2,492.7	7.2
	Total development	2,961	2,878.7	-2.8
	Total	5,652	5,234	-7.4



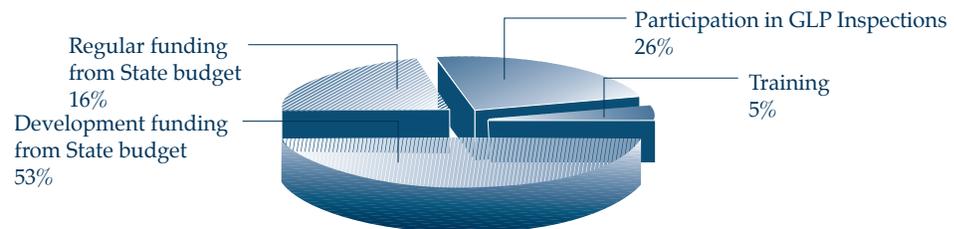
Forecast of Expenditure in the 2004 Budget in Comparison to the 2003 Budget:



Breakdown of Expenditure in 2003



Breakdown of Income in 2003

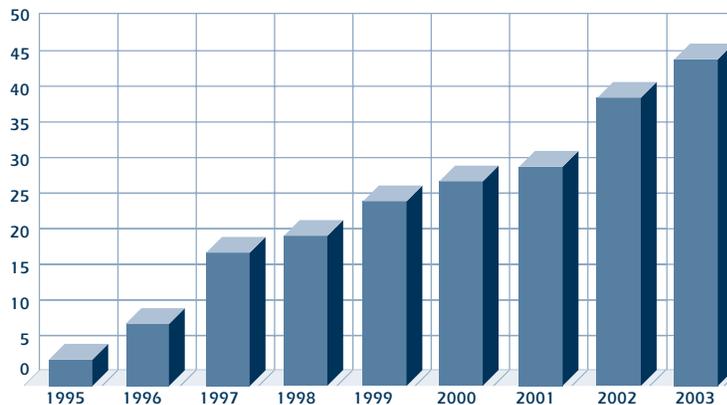




As of January 2004, 47 laboratories have received accreditation, and 6 research facilities received recognition to GLP. 12 laboratories are in the process of accreditation and 2 research facilities in the process of recognition.

Department	No. of accredited labs.	No. of labs. In the process of accreditation
Engineering	15	6
Biology & Chemistry	21	5
Calibration	11	1
GLP	6	2

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)



Laboratories interested in receiving full details of accreditation criteria are asked to purchase the kit "Explanations and Criteria for Testing / Calibration Laboratories Requesting Accreditation." In 2003, 14 laboratories/bodies purchased this document.



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, the 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 the accreditations, abstracts of some of the procedures, binding 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 2,300 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 it 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 of the accreditation process.

In addition to the above, the administrative guidelines binding ISRAC, as well as any other information (subject to ISRAC's confidentiality restrictions) may be read by any citizen at ISRAC offices, 8:30 AM - 5 PM, by prior arrangement.