

ISIRAC

Annual report Year 2000



Ministry of Industry & Trade



**הרשות הלאומית להסמכת מעבדות
Israel Laboratory Accreditation Authority**

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The Chairman's view

Shalom!

Strict compliance with high standards in all fields of activity is one of the central obligations of any modern state. This is particularly important in terms of ensuring the quality of the products and the services provided to its citizens, and has far-reaching ramifications for the exposure of Israeli products on the international market.

A fundamental principle in maintaining standards is the training of those bodies responsible for testing, to ensure that their standards are adapted to meet international norms and local needs. This is the function of the Israel Laboratory Accreditation Authority (ISRAC). ISRAC intends to extend the circle of accredited laboratories in diverse fields. In implementing these activities, priority will be given to aspects relating to safety, health and the environment. Over the past year, important steps have been taken toward ensuring international recognition for accredited laboratories, and consideration was given to ways of expanding and intensifying ISRAC's activities in new areas.

The executive board of directors and the management of ISRAC have set the objective of working together with the laboratory personnel and with governmental regulation bodies in order, ultimately, to provide the public with a high-quality and reliable service. In implementing these activities, ISRAC maintains high standards and maximum transparency. This annual report is one of the tools for presenting ISRAC's activities.

I wish ISRAC's clients ongoing and fruitful cooperation, and congratulate the ISRAC's management for their excellent work and achievements over the past year.

Sincerely,
Prof. Benjamin Geiger



2. The General Director's view



The Israel Laboratory Accreditation Authority is one of the main components of Israel's quality assurance infrastructure. Most of the advanced trading nations have signed agreements under the auspices of the World Trade Organization (WTO). As part of the quality infrastructure facilitating international trade, Israel has also established an authority responsible for the accreditation of laboratories, applying clear standards which comply with global activities.

Working according to international standards in harmony with other nations ensures confidence in measurement and testing systems applied in the State of Israel. This confidence is the foundation for the removal of non-tariff barriers.

ISRAC underwent profound managerial changes at the beginning of 2000. Most of the ISRAC's employees joined over the course of the year. ISRAC's mission, as formulated by the new staff, is **"to promote quality and professional competence of conformity assessment bodies in harmonization with the world, for the well being of the State of Israel and its citizens."** In order to fulfill this mission, all employees have devoted themselves to reorganizing the foundation of ISRAC's activities and to formalize ISRAC's policy and procedures.

One of the main objectives we set was to secure international recognition confirming that we provide accreditation in accordance with international standards. Such recognition will lead to signing of a Mutual Recognition Arrangement (MRA) between ISRAC and the umbrella organization of accreditation bodies - the International Laboratory Accreditation Cooperation (ILAC) - and the European body, EA (European Accreditation).

In November 15-17, 2000, ISRAC underwent a preliminary evaluation by Dr. Jorgen Blom (head of the team) from Denmark and Engineer Peter Unger, President of A2LA in the United States. In the evaluation, Engineer Peter Unger represented APLAC (the Asian Pacific Laboratory Cooperation) and ILAC, as head of the organization's Mutual Recognition Committee.

According to the evaluators, ISRAC was already prepared for the full assessment. Their opinion stated that "ISRAC has personnel at the highest professional level, as well as a quality system and procedures, which **fully** meet ISO/IEC Guide 58" (binding for accreditation organizations).

At the same time, ISRAC is working with representatives of the various government ministries and important opinion-making bodies in order to meet the needs of the Israeli economy.

Cooperation with the enforcement agencies (government ministries) will ensure that ISRAC can devote its main efforts to key issues of concern to the economy. This cooperation will also promote efficiency in the accreditation and recognition process for laboratories, saving resources for the laboratories and their clients.

ISRAC's policy is to focus mainly on promoting issues relating to international trade, industry, and national infrastructures. In its work, ISRAC prioritizes aspects relating to health, the environment, product quality and safety of use.



ISRAC's employees work energetically to disseminate the knowledge accumulated by ISRAC, as well as information about ISRAC, among clients, consumers and opinion-makers. There has been an upsurge in the number of potential clients contacting ISRAC. The process of improvement that the laboratories must complete in order to receive accreditation is time consuming, therefore; accordingly, it would be wrong to anticipate any significant increase in the number of accreditations in 2001. Based on trends at the end of 2000, a significant increase in the number of clients seems probable only in 2003. This trend depends on the condition of the economy and on the requirements imposed by the regulatory agencies.

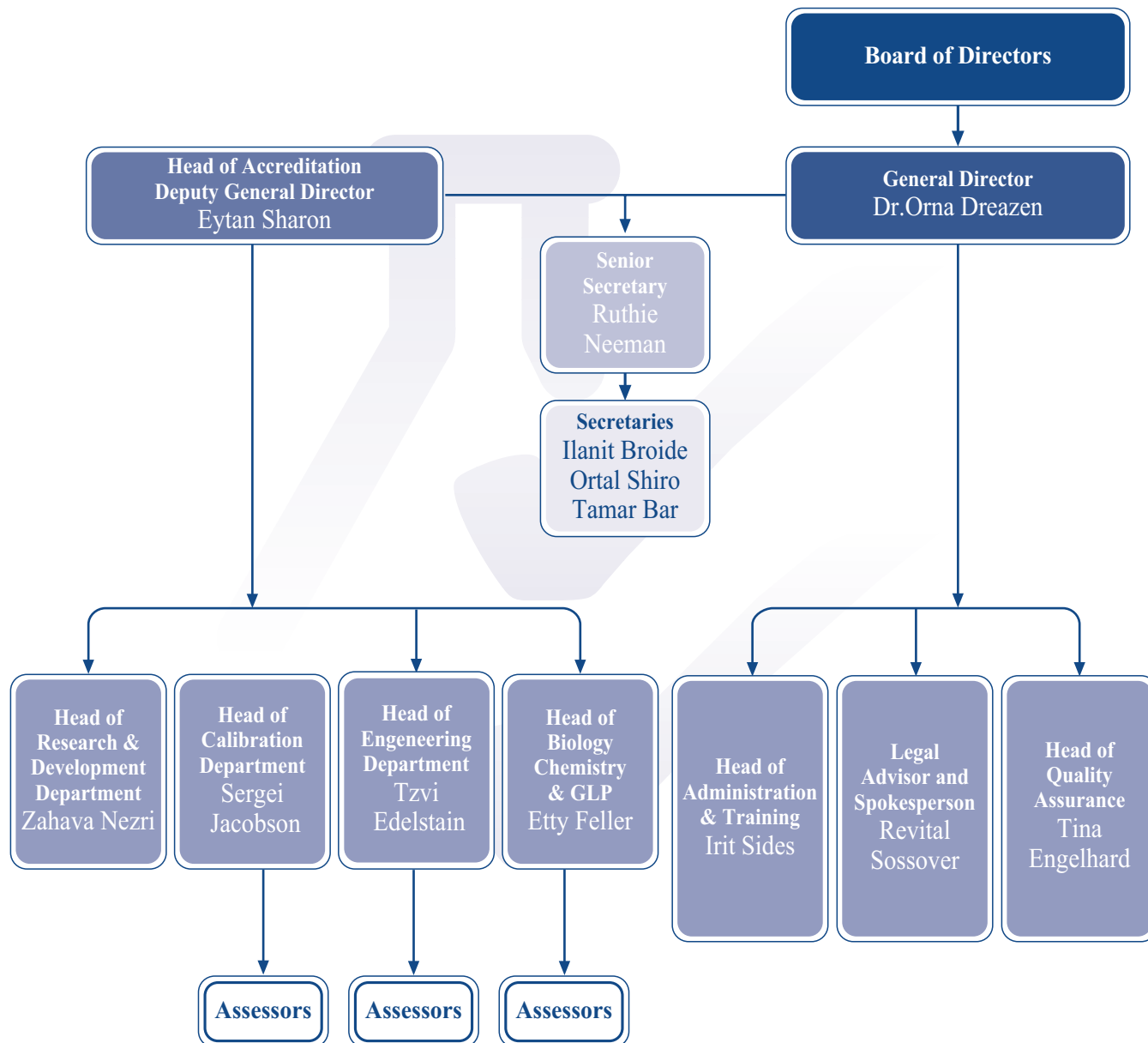
We hope that the dissemination of information by diverse means, transparency in ISRAC's operations, a high-quality and reliable service, and international recognition will help increase confidence in ISRAC on the part of the enforcement agencies in Israel. These bodies would do well to draw on the services of ISRAC, as a tool provided by the state in order to improve quality.

I would like to thank the Board of ISRAC for the confidence they have shown in the staff of ISRAC and myself. I also thank the laboratories for their cooperation, the government ministries, the economic organizations, and the devoted employees of ISRAC.

Dr. Orna Dreazen



3. Organization chart



4 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 other requirements of clients. 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 (the International Laboratory Accreditation Cooperation), whose function is to coordinate global accreditation policy. Israel is a full member of ILAC and signed a contract of cooperation with EA. ISRAC will sign an MRA with both organizations.

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 the passage of 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 accredit or annul the accreditation of laboratories.
- To serve as the exclusive representative of the state in all matters relating to mutual recognition of the accreditation 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 capability, thus constituting a means enabling clients and major consumers in the economy, such as the enforcement authorities, to acquire a reliable 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 and systems - General requirements for operation recognition.

ISRAC is currently in the process of securing recognition by ILAC and by the European regional organization EA. This process will culminate in the signing of a mutual recognition arrangement (MRA) between ILAC and ISRAC. The MRA will provide recognition by the 28 countries that have already signed MRAs for any test or calibration implemented 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 in the field of Good Laboratory Practice (GLP). The State of Israel has signed an MRA on the subject of GLP with the European Union, and is in the process of signing an MOU with the EPA in the United States. Israeli laboratories 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 with the GLP rules. ISRAC undertakes inspections according to the directives of the OECD, EPA or FDA.

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)
- Metals and Semi-metals
- Electricity
- Alcoholic beverages
- Health (Medical laboratories, Forensic and Medical research)

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:

- Food Additives
- Pharmaceuticals
- Cosmetics
- Pesticides
- Toxicants

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.

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." 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 standard, ISO/IEC 17025 or ISO/FDIS 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.

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 the sixty-seven members of ILAC, including the Western European nations, the United States, Japan, Australia, India, China and additional countries around the world.

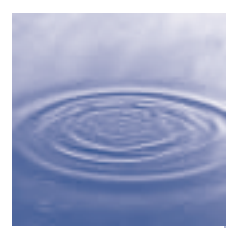


The quality system provides a tool ensuring that the laboratory will monitor its activities and draw conclusions in order to ensure constant improvement. Accreditation is recognized by the European governmental authorities and, in many cases, provides a basis for their recognition. Laboratories that 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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5. Principle Activities in 2000

The year 2000 was a year of transition and consolidation for ISRAC's staff. Many positions in ISRAC were vacant at the beginning of the year; only by June was the process of recruitment more or less completed. ISRAC employees met for two brainstorming days that focused on the strategic planning of ISRAC. These discussions led to the formulation of the basic values, ISRAC employees are expected to observe, as well as the vision and mission of ISRAC. The foundations were also laid for a detailed work plan based on objectives, according to the Balanced Score Card system.

ISRAC's employees defined the following key values to guide them in their work:

- Professionalism
- High-quality and reliable service
- Transparency

Objectives set for the end of 2000:

- Writing ISRAC's quality manual.
- Writing procedures for ISRAC's activities.
- Issuing a quarterly journal providing knowledge and information.
- Training ISRAC's assessors on the basis of the defined procedures.
- Training new assessors in additional fields.
- Expanding international contacts in order to secure mutual recognition.
- Initiating contacts with regulators in Israel in order to enhance the value of accreditation.
- Improving the ISRAC's Web site and using the site to achieve transparency.
- Acquiring knowledge and securing the confidence of international authorities in the field of GLP.

Objectives achieved in the year 2000:

- All the objectives relating to internal procedures in ISRAC were met in full within the set timetable. In November, ISRAC underwent pre-evaluation with great success. Evaluators' conclusion was that ISRAC has highly professional personnel and a quality system (procedures and quality manual) fully meeting the requirements of ISO/IEC Guide 58.
- Four issues of the "Reshuton" were issued during 2000, which included relevant articles on laboratory management and accreditation. ISRAC also published several of its procedures and binding guidelines for accredited laboratories and those seeking accreditation.
- Based on the provision in the ISRAC Law "to initiate ancillary activities to the accreditation of laboratories, such as training, publicity and information," ISRAC holds seminars, workshops and training programs for representatives of the laboratories, assessors and consultants in issues relating to the accreditation criteria.
 - In 2000, ISRAC held four seminars for its assessors, providing an opportunity for study, updates and the implementation of ISRAC's procedures and the accreditation criteria.
 - In September 2000, ISRAC held two courses for assessors of laboratories. The goal of the courses was to train additional assessors and refresh the knowledge of some of the veteran assessors. The courses were run on a workshop basis by experts from UKAS (United Kingdom Accreditation Services). A total of 40 representatives from 22 different bodies attended. The average feedback score was 4.13 out of 5.



- In September 2000, a one-day seminar and training session was held for representatives of the laboratories on the subject of adapting the quality system to meet ISO/IEC 17025 and interlaboratory comparative competence tests. 72 participants from 41 laboratories attended the seminar; the average feedback score was 4.37 out of 5.
- ISRAC representatives participated in international courses and assessments in the field of GLP in order to expand their knowledge and develop contacts and confidence with personnel in the European Union and the American agencies (FDA and EPA). At the monitoring meeting held at the end of November, the representatives of the European Union noted ISRAC's progress and approved its quality Manual in the field of GLP (the manual appears on ISRAC's web site). By the next annual meeting (September 2001), the representatives will recommend the completion of the transitional phase in the MRA and recognition of ISRAC's activities.
- ISRAC's General Director continued her predecessors involvement on ILAC's main technical committee (Technical Accreditation Issues). At the general meeting in November, she was elected to represent the unaffiliated bodies on the executive committee of ILAC, and participates in the organization's finance committee. The General Director is also active on the parallel committee in the EA (the Laboratory Committee).
The Deputy General Director of ISRAC is an active committee member in the International Accreditation Forum (IAF). ISRAC representatives held mutual visits to A2LA in the United States, UKAS in Britain, SWEDAC in Sweden and DAR in Germany. These visits help promote mutual exchanges of ideas and techniques.
ISRAC's quality manager is a member of the team preparing the criteria for evaluating accreditation organizations. Each of the department heads are members of an international working group active in his/her field of work.
ISRAC executive staff also expresses its opinions on documents produced by ILAC and are partners in drafting these documents, with equal voting rights (one vote per economic unit) in their acceptance or rejection.

Principle activities planned for 2001

In 2001, ISRAC will concentrate on the following activities:

- The international assessment and signing the international MRA.
- Re-examining ISRAC's processes in order to prepare for growth.
- Re-accreditation and surveillance of laboratories, to ensure compliance with ISO/IEC 17025.
- Developing the accreditation process in new fields, such as medical laboratories, smoke detectors and sprinklers, game fields, etc.
- Participating in international laboratory comparisons.
- Expanding cooperation with the EA and ILAC.
- Contacts with regulators for enhancing the value of accreditation.
- Information and marketing ISRAC's activities.
- Inculcating knowledge and training in areas relating to quality management in laboratories.



Budget for 2000 and 2001

Budget for 2000 and 2001

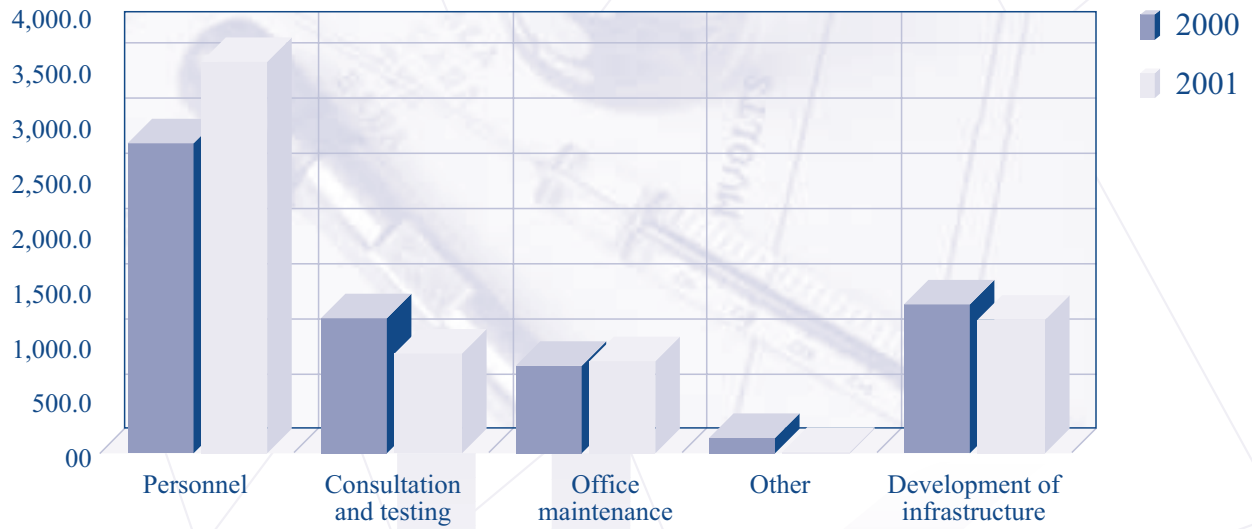
	2000 budget	2001 budget	Nominal change
	NIS 000's	NIS 000's	%
Expenditure			
Regular operations	3,230.3	3,491.7	8.1
Development	3,087.7	3,022.8	-2.1
Total Expenditure	6,318.0	6,514.5	3.1
Income from Operations			
Accreditation and surveillance	1,380.0	1,577.5	14.3
Training and GLP inspections	<u>96.0</u>	<u>122.0</u>	<u>27.1</u>
Total Income from Operations	1,476.0	1,699.5	15.1
Income from Funding			
Funding of development - State budget	3,087.7	3,022.8	-2.1
Regular funding - State budget	1,754.3	1,792.2	2.2
Total Income from Funding	4,842.0	4,815.0	-0.6
Total Income	6,318.0	6,514.5	3.1

Expenditure

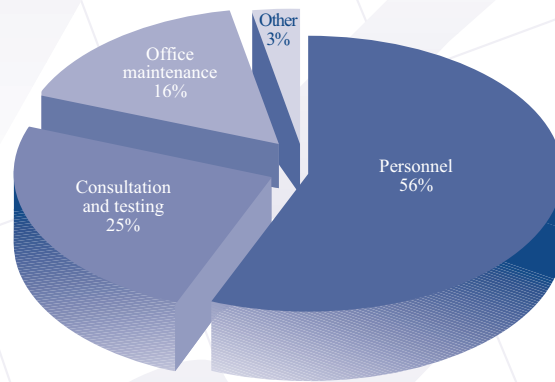
		2000 budget	2001 budget	Nominal change
		NIS 000's	NIS 000's	%
Expenditure				
1.0	Personnel	2,802.4	3,535.6	26.2
2.0	Consultation and testing	1,226.0	904.7	-26.2
3.0	Office maintenance	791.8	842.0	6.3
4.0	Other	151.8	15.2	-90.0
	Total operating expenditure	4,972.0	5,297.5	6.5
	Development element	(1,741.7)	(1,805.8)	
	Total regular operations	3,230.3	3,491.7	8.1
5.0	Infrastructure Development	1,346.0	1,217.1	-9.6
	Development components	1,741.7	1,805.8	
	Total development	3,887.7	3,022.8	-2.1
	Total	6,318.0	6,514.5	3.1



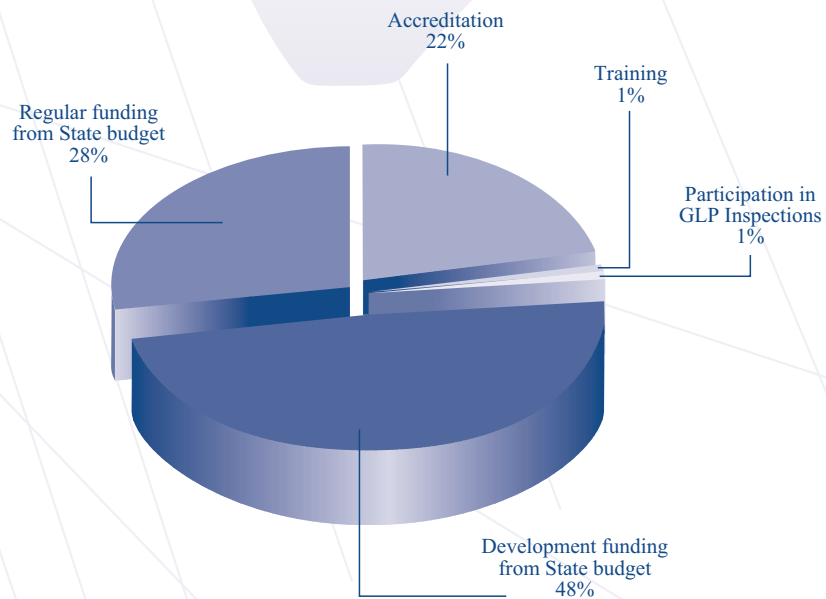
Forecast of Expenditure in the 2000 Budget in Comparison to the 2000 Budget



Breakdown of Expenditure in 2000



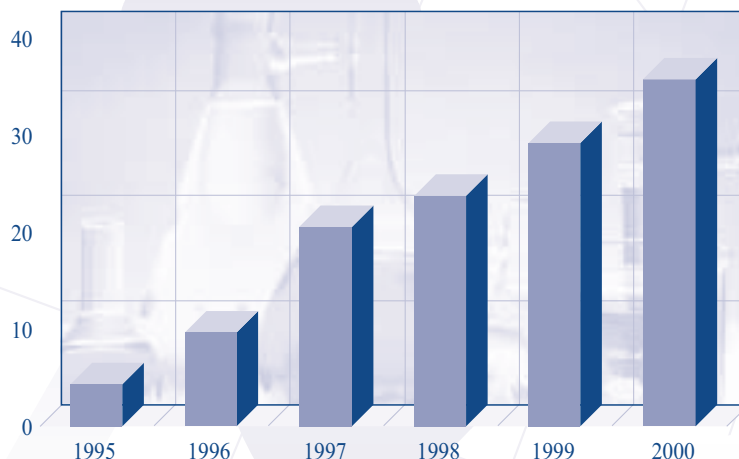
Income



As of January 2001, 33 laboratories have received accreditation. Another 13 laboratories are in the process of accreditation.

Department	No. of accredited labs.	No. of labs. In the process of accreditation
Engeneering	10	2
Biology & Chemistry	10	5
Calibration	9	5
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):



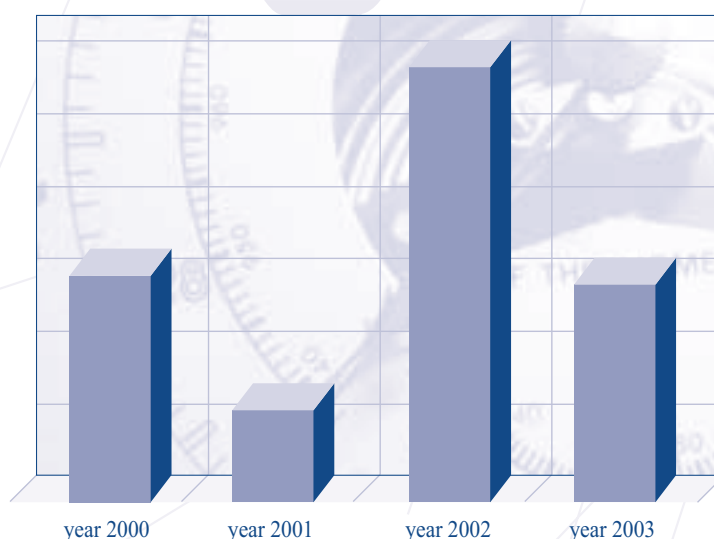
Laboratories interested in receiving full details of accreditation criteria are asked to purchase the kit "Explanations and Criteria for Testing / Calibration Laboratories Requesting Accreditation."

In 2000, 16 laboratories/bodies purchased these documents.

In accordance with the ISRAC Law, the period of accreditation is defined by ISRAC's board. As of the beginning of 2001, the period of re-accreditation is 3 years for the first re-accreditation, and 4 years for each subsequent re-accreditation.

These data are reflected in the three- and four-year cycles in the overall income from re-accreditation.

Cyclical Pattern of Income from Re-accreditation:



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. Information on the accreditation process is also available in English.

Each quarter, ISRAC publishes a journal "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 1,400 readers each quarter, 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.

