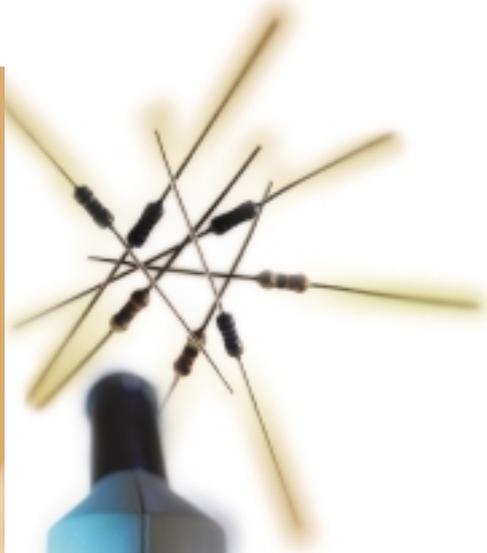




Ministry of Industry & Trade



ISRAC
Israel Laboratory Accreditation Authority



Annual Report

Year
2001





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Shalom!

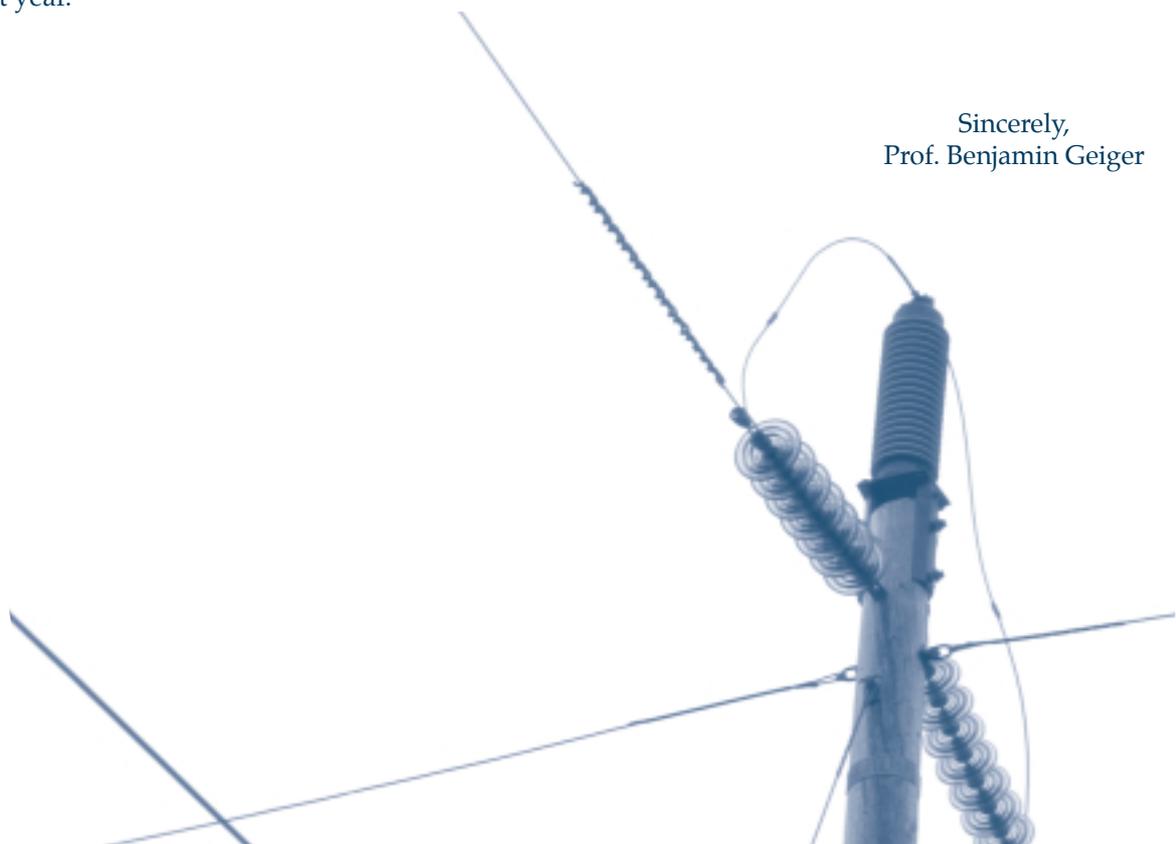
The strict compliance with high standards in all areas of activity is one of the central obligations and mark of recognition of any modern state. This is crucial for maintaining the quality of goods and services it provides, and for bringing Israeli products to the attention of the international market.

The fundamental principle in maintaining standards is to train the entities who perform the testing, and to guarantee that their standards comply with international norms and local needs. This is the role of the Israel Laboratory Accreditation Authority (ISRAC). It intends to increase the circle of accredited laboratories in various fields, in an effort to ensure that all laboratories are accredited, provide the highest level of services, and benefit from the advantages that come with accreditation. In expanding and intensifying its activity, priority will be given to those aspects relating to safety, health and the environment. Moreover, in the past year we have made important strides in the international field including a broad recognition of accredited laboratories.

ISRAC's management and its Board of Directors are determined to work together with laboratory personnel and government regulatory bodies in order, ultimately, to provide the public with reliable, high quality service. In so doing, ISRAC will maintain the highest standards and maximum transparency, and this annual report is one of the tools used to present ISRAC's activities.

I wish all the accredited laboratories continued cooperative and productive work, and I congratulate all of ISRAC's dedicated staff and management for their excellent work and accomplishments over the past year.

Sincerely,
Prof. Benjamin Geiger





The Israel Laboratory Accreditation Authority (ISRAC) constitutes an important element of Israel's quality infrastructure. In the past year, ISRAC has endeavored to obtain international recognition of its work and recognition of the test and calibration certificates it issues in Israel bearing the ISRAC logo. ISRAC has undergone an international peer evaluation by representatives from Europe and the United States and has been greatly praised for its operations. The evaluation touched on all operational elements and the degree to which they comply with the international standard ISO/IEC Guide 58, terms specified in the ILAC agreements, and other provisions published by ILAC.

As a result of the aforementioned international evaluation, ILAC signatories invited ISRAC to sign a mutual recognition agreement. The votes held in ILAC and the EA were by consensus and ISRAC earned special recognition from those participating in the discussions, particularly for its excellent system that has been established, its transparency and its compliance with requirements. The mutual recognition agreement was signed with ILAC and the EA in November 2001.

The year 2001 was also the transition year for implementing the ISO/IEC 17025 standard. This standard includes important topics that were not emphasized in the ISO/IEC Guide 25, such as sampling, an expanded uncertainty evaluation, contract review, etc. In light of these changes, ISRAC was required to provide training for laboratories and its assessors. This training also included the development of policies and practices to help facilitate the implementation of these issues. Furthermore, professional advisory committees were established for the fields of construction and medicine, in order to discuss the professional problems resulting from the implementation of the new standard.

In 2001 ISRAC became active in the field of medical laboratories. This special area required much development work on ISRAC's part and the formulation of special practices for this sector. In cooperation with the Israel Society for Clinical Laboratory Sciences, an advisory committee was established representing most of the disciplines in the field. The committee assisted ISRAC in defining the scope of accreditation for medical laboratories. In the future, the committee will be expanded to include physicians in order to enhance understanding of the needs of medical laboratories customers. A pilot program for working with medical laboratories has been announced. To date three hospitals, a public laboratory and a private laboratory have joined the program and have begun implementing ISO/IEC 17025 standard while using ISO/DIS 15189 as a guidance document for medical laboratories. ISRAC has developed preliminary guidelines for medical laboratories, and the process is currently in progress. In parallel to this process there is ongoing cooperation with the ministry of health.

In the beginning of 2002, cooperation with the Ministry of the Environment has intensified. This cooperation is reflected in the assistance given to ministry personnel in defining the requirements from the laboratories they receive test results from, and in defining a basis for comparing laboratory results.

In the construction field, an advisory committee was established consisting of Israel's finest experts and representatives from the laboratories and various government ministries. The role of the committee is to discuss issues such as sampling, identifying the location for measurement etc. The committee is to recommend a series of requirements from construction laboratories, as well as the need for changes in standards and regulations in order to obtain significant results for the benefit of Israel's citizens.



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We have continued to publish ISRAC's newsletter, the *Reshuton*, on a quarterly basis, and its circulation has increased from 200 to 2000 copies. Those who receive it, confirm that it includes material that they find valuable.

In 2001, ISRAC published a Service Charter and is conscientious in complying with it. In a survey, our customers indicated their satisfaction with the major reforms that have taken place within ISRAC and how it is managed.

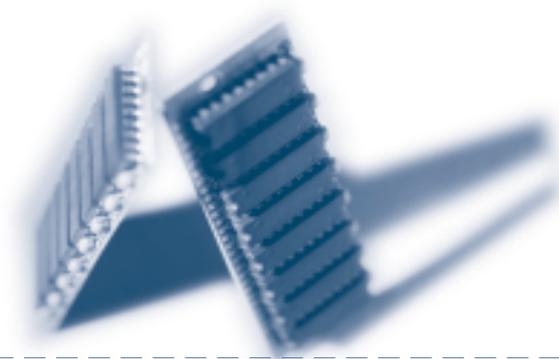
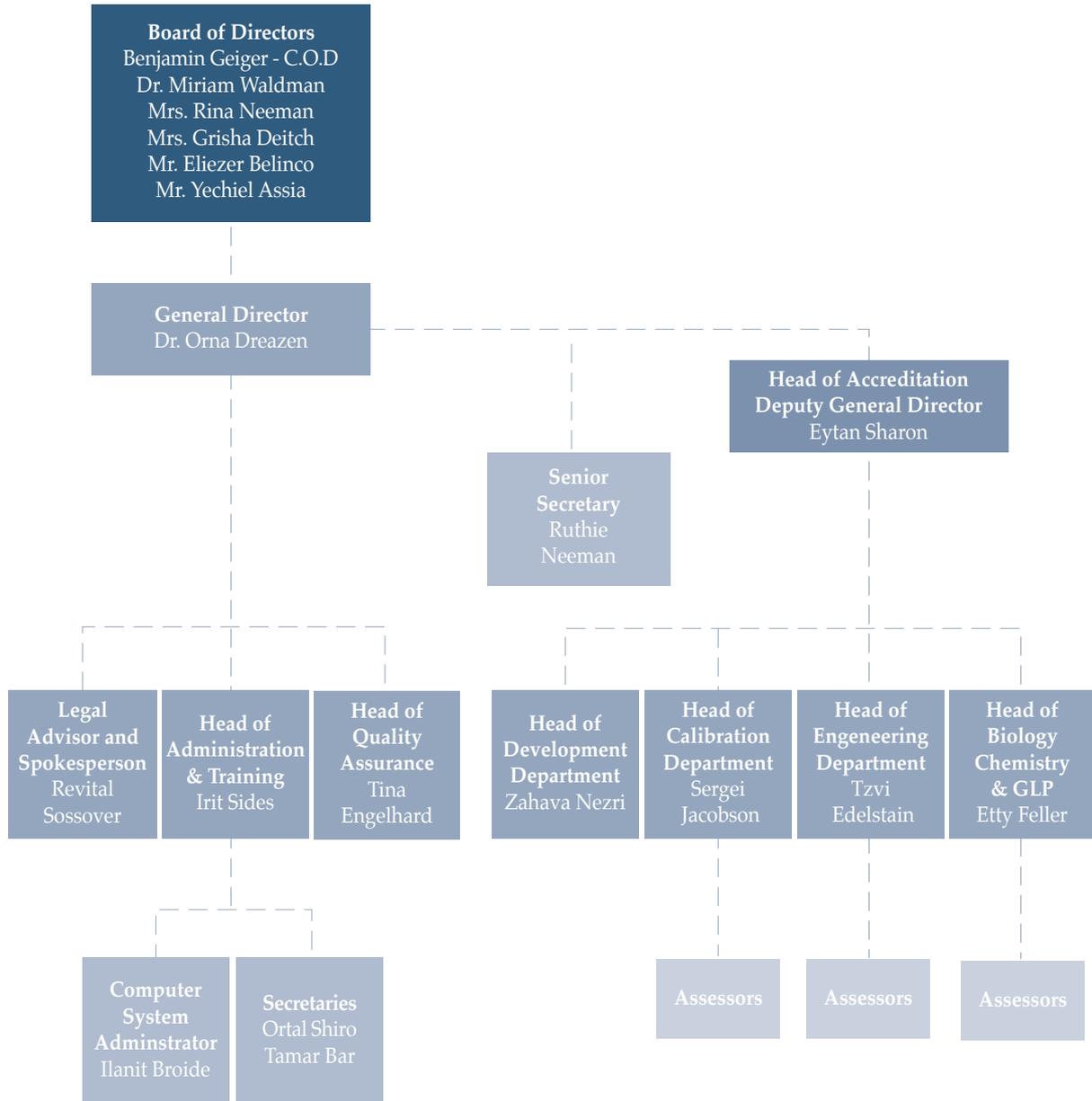
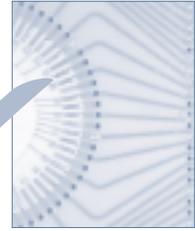
ISRAC's employees are aware of the need for constant improvement and they are involved, on a year-round basis, in learning from their operations.

I wish to thank our customers and the regulatory bodies with which we work. The trust they have placed in us, and to thank ISRAC's employees for their ceaseless dedication.

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.

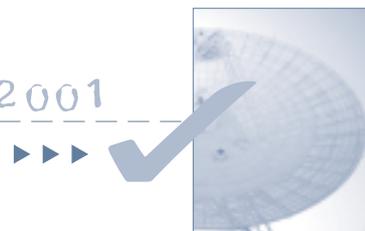
In August of the same year, the committee presented its recommendations, stating that there was an urgent need to establish a national system for the accreditation of laboratories. Following this, the minister decided in 1993 to establish the Israel Laboratory Accreditation authority (ISRAC); an advisory 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 32 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 an MRA with the European Union, and is in the process of signing an MOU with the EPA in the United States. 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 with the GLP directives. 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
- Environment
- Electricity
- Alcoholic beverages
- Health (Medical laboratories, Forensic and Medical research)
- Lifting Devices

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." 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 (1999) 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:

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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Senior Secretary	Ruthie Neeman		03-5751690(207)	ruthien@israc.gov.il
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Secretary	Ortal Shiro		03-5751690(201)	ortals@israc.gov.il



During 2001 ISRAC personnel focused on establishing its status at home and abroad. In discussions held during strategic planning seminars, it was decided to dedicate efforts towards marketing within Israel, along with intensifying international activity.

Goals established for 2001:

- Signing of an international mutual recognition agreement.
- Re-examination of work processes to encourage growth.
- Inspection of laboratory compliance with the ISO/IEC 17025 standard.
- Development of accreditation processes in new fields such as medical laboratories, smoke detectors and sprinklers, lifting devices, and others.
- Participation in international comparative proficiency testing
- Intensification of cooperation with EA and ILAC.
- Contact with regulatory authorities and increasing the value of accreditation.
- Public relations for and marketing of ISRAC's activities.
- Transmission of knowledge and training in fields connected with quality management.

Achievements during 2001

- In November 2001, two mutual recognition agreements were signed with ILAC and with EA.
- ISRAC's procedures were reviewed. During the course of the year, a recommendation was made to ISRAC's council to extend the period of re-accreditation from three to four years. This recommendation was approved by the Council.
- ISRAC's assessors were instructed in conducting assessments in accordance with ISO/IEC 17025. Similarly, the significant differences between the new standard and its predecessor were clarified. All surveillance and re-accreditation assessments that were carried out this year were performed in accordance with this standard. Laboratories were required to complete the process of adopting the new standard and to carry out all corrective actions by the end of the year.
- The Head of Development Department was involved in working with medical laboratories as part of the pilot program, which a limited number of laboratories were permitted to join. In this framework, the special problems arising for this sector in connection with implementation of the practices of the ISO/IEC 17025 standard are being looked into.
A checklist, based on a draft of the ISO/DIS 15189 standard for medical laboratories, has been developed. This list includes terminology that is appropriate for medical laboratories, and can be seen as a clarification of questions that are likely to arise from the general standard ISO/IEC 17025. For the convenience of the laboratories that underwent certification on the basis of the 1994 version of ISO/IEC 9002, the checklist emphasizes the sections that are common to the two standards. This approach allows the laboratories interested in undergoing accreditation to identify the topics they must upgrade.
At the same time, a professional advisory committee was set up within ISRAC in conjunction with the Israel Society for Clinical Laboratory Sciences. This Committee was given the following roles:
 - To advise the General Director on questions that raised during the medical laboratories' preparation for accreditation.
 - To formulate documents on the scope of accreditation for medical laboratories.
 - To formulate training documents for laboratories and their assessors, according to ISO/DIS 15189 and ISO/IEC 17025.



The Committee is active and so far has helped produce an appendix to “Explanations and Requirements for Testing and Calibration Laboratories Seeking Accreditation”, which deals with defining the scope of accreditation for medical laboratories.

- For the purpose of accrediting laboratories in connection with smoke detectors and sprinklers, a reservoir of professional questions was developed at ISRAC to constitute a basis for assessing the engineers working in this field. Assessments of these laboratories are composed of two parts: Examination of the knowledge for evaluating professional expertise and a thorough knowledge of the relative standards on the one hand, and an assessment of how tests are executed at the site where these systems are installed on the other hand. The surveillance and assessments are carried out in cooperation with the fire and rescue commission and the commissioner of standardization. This activity has also been recognized by them.
- Accredited laboratories took part in inter-laboratory comparative proficiency testing and corrective actions. The laboratories undertook to submit the test results to ISRAC as well as implement the conclusions derived from the results. The response was relatively good, even if the time schedule was not always adhered to in full. This issue was assessed during surveillance visits. Such tests can be obtained abroad in most areas in which the accredited laboratories are involved. The calibration laboratories took part in the EA interlaboratory comparisons ILC-T2 (moment) in the M-23 (length), F-3 (force) and Th-10 (temperature) programs, according to the dates established by the organizing body. In addition, EA and APLAC, have organized two on-going comparisons among the laboratories dealing with egg powder for pesticide compounds (from India), microbiology in food (from China) and a chemistry test for water, which concluded at the end of the year 2001.
- In the international context, confidence was expressed in our representatives participating in most central committees of ILAC and EA. In ILAC, ISRAC representatives are members of the following committees:
 - The Executive Committee.
 - Technical Accreditation Issues Committee
 - Accreditation Policy Committee
 - Arrangement Management Committee
 - Key Performance Indicators CommitteeIn the context of the EA, ISRAC’s representative is a member of the Laboratory Committee.
- ISRAC’s representatives work with the EU and the American EPA and FDA to earn their recognition in the area of inspections in accordance with GLP directives for pre-clinical research, as preparation for the registration of pharmaceuticals, cosmetics, toxicants, pesticides, and food additives. Contacts with the American bodies are carried out with the support of the US Science and Technology foundation. In addition, ISRAC’s General Director is a member of the ISO / TC 212 Committee as a representative of ILAC and the Israel Standards Institute. The committee is involved in writing standards for medical laboratories and medical devices.
- ISRAC has intensified its connection and cooperation with the Ministries of the Environment, Health and Transportation. In some instances it led to definition of the conditions under which the accreditation supports the government policy. In various spheres, such as testing the air in chimneys, the Ministry of the Environment announced that after a specified period of time, it would require laboratories to be accredited by ISRAC in order to receive Ministry recognition.



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- ISRAC employees worked on public relations and marketing ISRAC's activities. Marketing has been done with various interested entities. In addition, ISRAC held detailed meetings with representatives of government ministries and large companies. ISRAC's Deputy General Director participates regularly in the Quality Forum conducted by the Defense Ministry's Director of Purchasing. A new Internet site has been developed.
- ISRAC publishes the "Reshuton", which includes articles and explanations about its activities, the requirements of the standard and professional topics related to the laboratories' work. The material published in the Reshuton is also found on ISRAC's Internet site: www.israc.gov.il.
- During the year 2001, the following courses were held:
 - Uncertainty for test methods, control charts and validation
 - The ISO/DIS 15189 standard for medical laboratories.
 - The ISO/IEC 17025 standard and inter-laboratory test comparisons.
 - Internal calibration in testing laboratories.
 - Discussion and training for calibration laboratories.
 - Quality management in a medical laboratory according to the proposed ISO/DIS 15189 standard.
 - The ISO/IEC 17025 standard for testing and calibration laboratories, ISRAC's requirements, and preparation for implementation.
 - Special emphases in the ISO/IEC 17025 standard as preparation for the 2002 assessments.
 - Workshop for writing procedures.
 - Workshop: Internal calibration in testing laboratories.
 - Accreditation of medical laboratories from the point of view of the director of an accredited medical laboratory.
 - Types of scopes of accreditation and sampling in accordance with the requirements of ISO/IEC 17025.

ISRAC's representatives took part in conferences of electrical engineers, of certification organizations and of laboratories which carry out non-destructive testing, a forum of employees and directors of medical laboratories, etc.



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Main Activities Planned for 2002



- Recognition by the European Union, the United States and the OECD countries of the recognition system for research facilities that operate in accordance with GLP principles.
- Re-evaluation of work procedures so as to achieve constant improvement.
- Re-accreditation and surveillance of laboratories for implementing ISO/IEC 17025.
- Inspection of laboratories that are recognized according to GLP principles.
- Accreditation of new laboratories in new fields such as chimney-testing, hazardous dusts, medical laboratories, forensic and medical research, etc.
- Public relations and marketing of the ISRAC's activities and the ILAC MRA.
- Transmission of knowledge and training in fields related to quality management in the laboratories.
- Establishing a uniform database for the accredited laboratories.
- Enhancing the ISRAC's new Internet site.

Budget for 2001 and 2002



Budget for 2001 and 2002

	2001 budget	2002 budget	Nominal Change
	NIS 000's	NIS 000's	%
Expenditure			
Regular operations	3,491.7	3,428.7	-1.8
Development	3,022.8	3,191.3	5.6
Total Expenditure	6,514.5	6,620.0	1.6
Income from Operations			
Accreditation and surveillance	1,627.5	1,770.0	8.8
Training and GLP inspections	72.0	275.0	281.9
Total Income from Operations	1,699.5	2,045.0	20.3
Income from Funding			
Funding of development - State budget	3,022.8	3,191.3	5.6
Regular funding - State budget	1,792.2	1,383.7	-22.8
Total Income from Funding	4,815.0	4,575.0	-5.0
Total Income	6,514.5	6,620.0	1.6

Expenditure

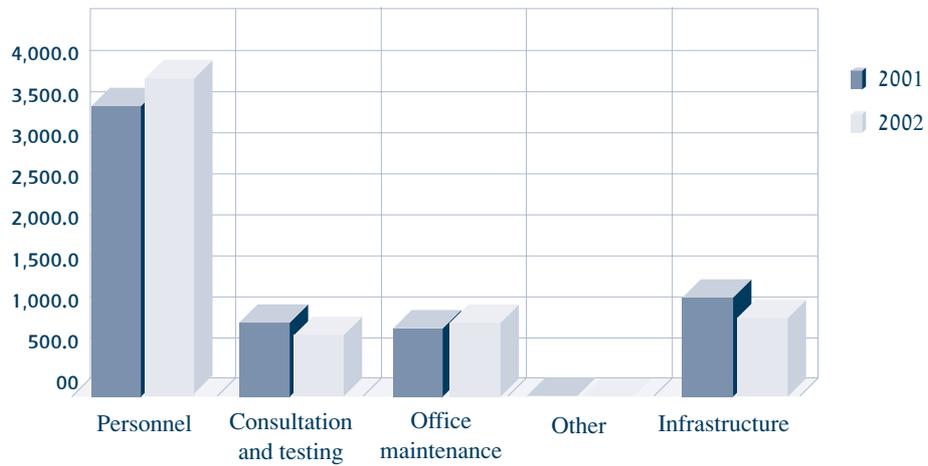
		2001 budget	2002 budget	Nominal Change
		NIS 000's	NIS 000's	%
Expenditure				
1.0	Personnel	3,535.6	3,972.0	12.3
2.0	Consultation and testing	904.7	776.0	-14.2
3.0	Office maintenance	842.0	905.0	7.5
4.0	Other	15.2	15.0	-1.3
	Total operating expenditure	5,297.5	5,668.0	7.0
	Development element	-1,805.8	-2,239.0	24.0
	Total regular operations	3,491.7	3,429.0	-1.8
5.0	Infrastructure	1,117.1	952.0	-14.8
	Development components	1,905.8	2,239.0	17.5
	Total development	3,022.8	3,191.0	5.6
	Total	6,514.5	6,620.0	1.6



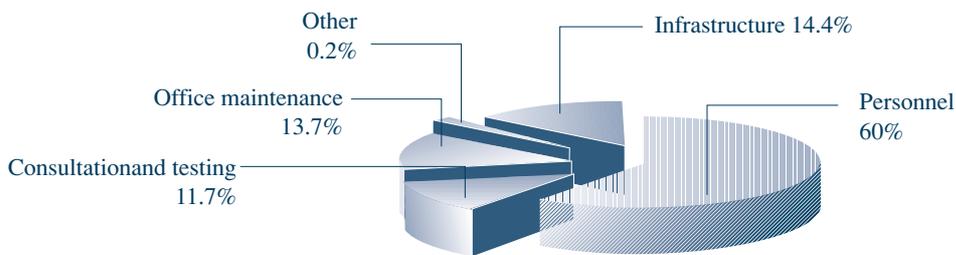
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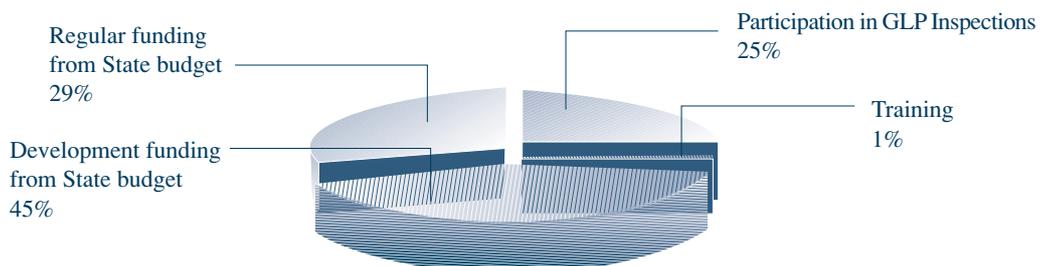
Forecast of Expenditure in the 2002 Budget in Comparison to the 2001 Budget:



Breakdown of Expenditure in 2001



Breakdown of Income in 2001





As of February 2002, 34 laboratories have received accreditation. Another 12 laboratories are in the process of accreditation.

Department	No. of accredited labs.	No. of labs. In the process of accreditation
Engeneering	11	2
Biology & Chemistry	13	5
Calibration	10	5
GLP	5	0

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 2001, 18 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 thier scope of accreditation, as well as ISRAC guidelines and extensive additional information. ISRAC's web site is bilingual (Hebrew & English).

Each quarter, 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 2,000 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.