



Ministry of Industry, Trade & Labor



**ISRAC**  
Israel Laboratory Accreditation Authority



# Annual Report

Year  
**2002**





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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 strictly 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.

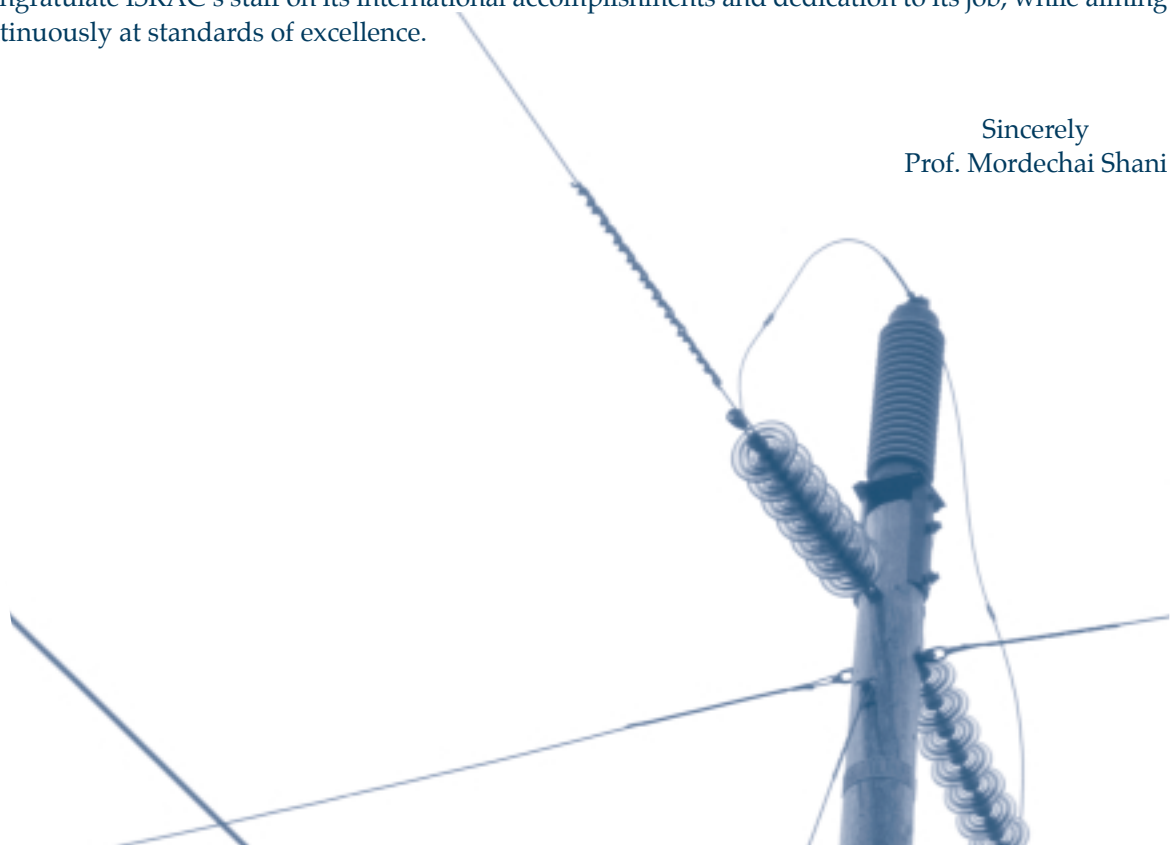
ISRAC's first priority is to take care of matters involving health, safety and the environment. As a result, ISRAC has been busy last year with expanding its knowledge and enabling the accreditation of laboratories working on these subjects.

With my appointment as ISRAC's chairman I shall act to deepen the awareness of its activities in everyday life, while providing transparent and credible services to laboratories and different regulators who rely for their decision-making on accredited laboratories.

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





The Israel Laboratory Accreditation Authority (ISRAC) plays a pivotal role in the qualitative infrastructure of the State of Israel. In the year 2002 ISRAC worked hard to expand its activities to new areas, in accordance with the priorities set by its council. The first medical laboratory – the central blood bank of Magen David Adom, was granted accreditation in 2002. Additional medical laboratories are preparing themselves for accreditation, which hopefully will be granted during 2003.

ISRAC accompanied the preparations for accreditation of the first medical laboratories, implementing a pilot plan which started at the beginning of the year. These laboratories operate according to a special standard for medical laboratories ISO 15189, which was published in the beginning of 2003. ISRAC's involvement within the ISO organization in the preparation of this new standard made it possible to start working according the ISO 15189 while it was still under preparation.

Although medical laboratories constitute only a small part (less than 5%) of the health system's budget, it is known that approximately 75% of medical decisions are based on results obtained from these laboratories. Investing in the quality of medical laboratory testing should therefore improve decision-making, reduce suffering and save unnecessary treatments and costs.

In accordance with the decision of ISRAC's Council, the first laboratory for testing of pressure vessels was granted accreditation. We hope that our involvement in this area, as well as in that of lifting devices, will result in an improvement in the level of testing and, accordingly, in the safety of pressure vessels and lifting devices, to the benefit of the public.

Following the decision of the home front command, ISRAC has added the public shelter tests to the scope of the accredited laboratories. This had to be done before the start of the war in Iraq.

In 2002, the laboratories completed the transition to the ISO/IEC 17025 working standard. A lot of effort has gone in adjusting to this standard. The laboratories have invested a great deal of work in the contract review to ensure that their services match customers' needs. In this issue, ISRAC was tried to help the laboratories by publishing requirements in several issues of ISRAC's bulletin to explain its point of view. The first requirements were intended for the calibration laboratories. This was followed by an half day seminar held for the customers of the calibration laboratories, to improve communication and understanding between customer and service provider. It proved to be a successful initiative, which met with an enthusiastic response.

In addition, much work has been invested by the laboratories in validating the test methods, estimating the uncertainty of the results and other subjects of importance in the new standard.

In 2002, accreditation was granted, for the first time, to laboratories for sampling and opinions and interpretations. Furthermore, for the first time the accreditation scopes were granted to include type C.

A big project, in which ISRAC invested much time, was the reformulation of the documents concerning the scope of accreditation. This project was carried out with full cooperation of the accredited laboratories, whose comments we tried to implement. It was done for the benefit of the laboratories' customers, who found it difficult to compare the accreditation scopes of different laboratories. The uniformity in scope will also allow the creation of a search engine, which will make it easier for the customers to find their way through the many detailed documents describing the laboratories' accreditation scope.

We hope that the new formulation is clearer and easier to use. We will be pleased to hear your comments.



ISRAC's employees do their best to streamline the work on the one hand, and to increase the quality of accreditation on the other hand.

Increased efficiency is obtained by a change in accreditation assessment and pricing methods. According to the new method, accreditation assessments are performed to examine all professional aspects of the laboratories, thus enabling less extensive surveillance assessments. The purpose of the new pricing method is to achieve greater transparency and to allow the laboratories to plan their budget, while encouraging the laboratories to apply for accreditation for all tests using accredited technologies. This should prevent the misleading of the public. Nevertheless, we request the public to examine the laboratory's accreditation scope and to make use of their services in an intelligent way.

In order to increase the value of accreditation, ISRAC cooperates with most of the regulators in Israel. In addition, an agreement of understanding with respect to GLP was signed with the EPA. ISRAC was officially invited to represent the State of Israel in the GLP committee of the OECD. We hope to be recognized by these two organizations during 2003.

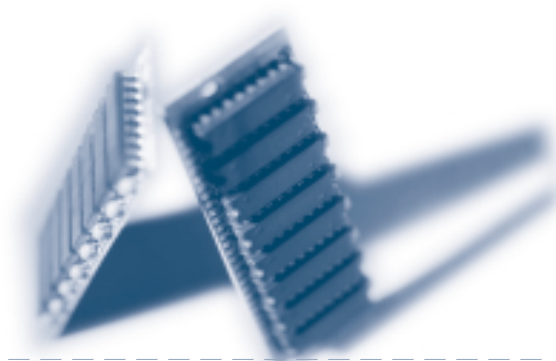
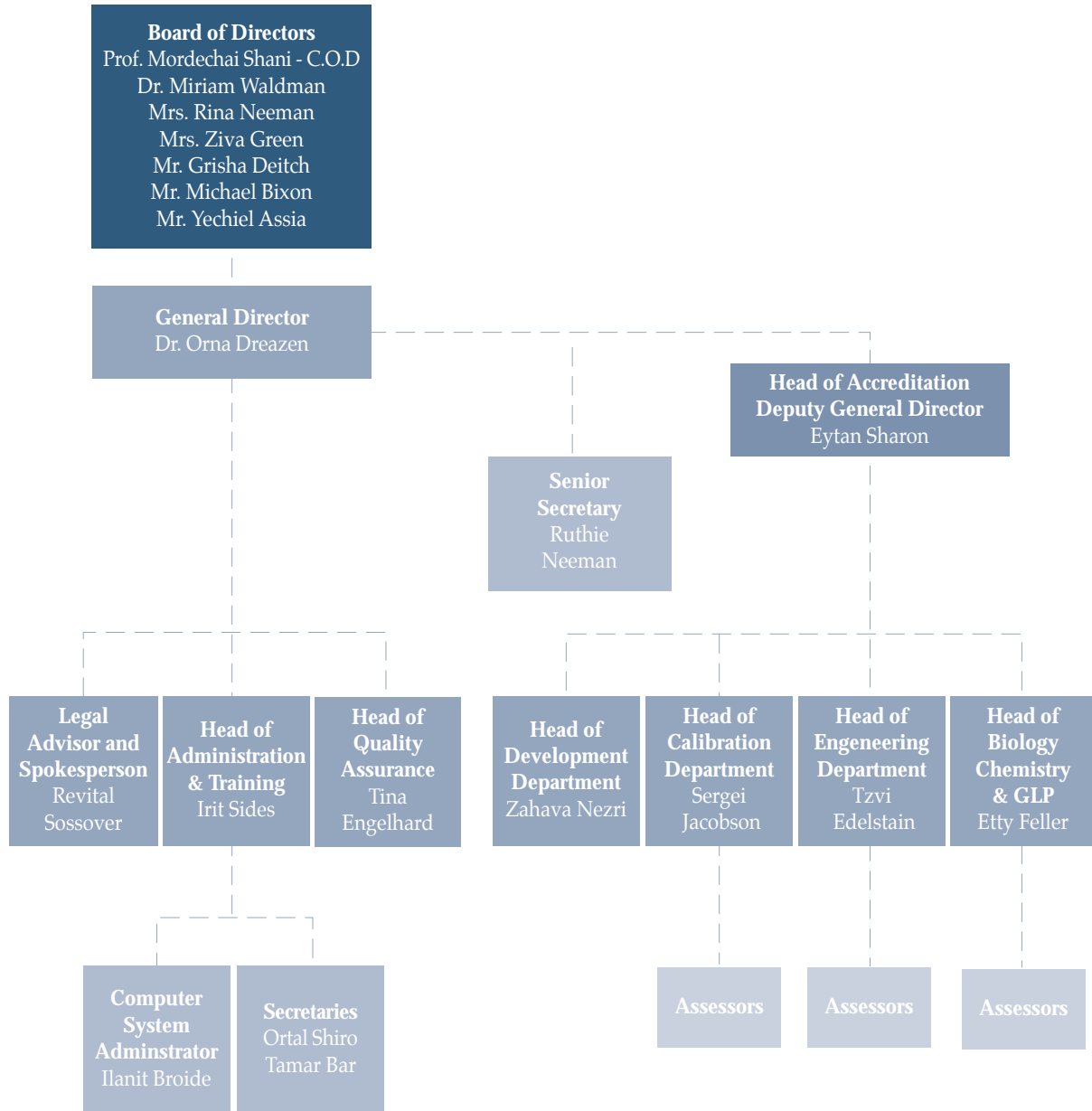
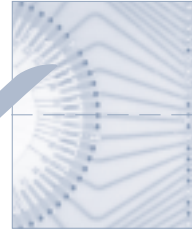
Concerning international activities, there are contacts between the Israeli and American Ministries of Communication (FCC), to enable recognition of accredited laboratories by ISRAC.

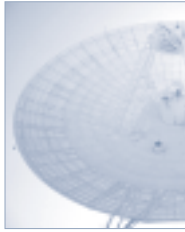
I sincerely hope that the number of accredited laboratories shall continue to grow and that the quality of testing shall improve. I am grateful to our customers and the regulatory authorities with which we cooperate for the trust they put in us, and to ISRAC's employees for their ongoing efforts and the enormous investment they made in improving the quality.

Dr. Orna Dreazen



Annual Report 2002  
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 2002 five 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:

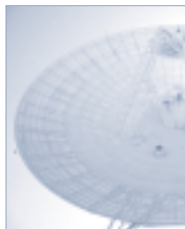
#### Types of tests

- 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)
- Metals and Semi-metals
- Environment
- Electricity
- Alcoholic beverages
- Health (Medical laboratories, Forensic and Medical research)
- Lifting Devices
- Perssure vessels

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

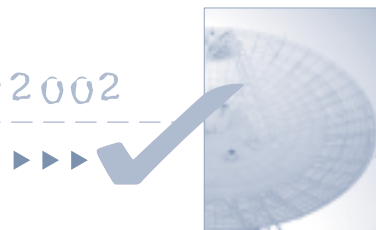
ISRAC's criteria and rules for the accreditation of laboratories are based on the international standard ISO/IEC 17025-1999: "General requirements for the competence for testing and calibration laboratories." Medical laboratories are accredited according a specific standard, ISO 15189, which is based 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](http://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](mailto:israc@israc.gov.il), **Web Site:** [www.israc.gov.il](http://www.israc.gov.il)

Position	Position			
General Director	Dr. Orna Dreazen	Ph.D	03-5751690(208)	<a href="mailto:ornad@israc.gov.il">ornad@israc.gov.il</a>
Head of Accreditation Deputy General Director	Eytan Sharon	M.Sc, C.Q.E	03-5751690(219)	<a href="mailto:eytans@israc.gov.il">eytans@israc.gov.il</a>
Head of Calibration Department	Sergei Jacobson	M.Sc	03-5751690(205)	<a href="mailto:sergeij@israc.gov.il">sergeij@israc.gov.il</a>
Head of Engineering Department	Tzvi Edelstain	M.Sc	03-5751690(204)	<a href="mailto:zvie@israc.gov.il">zvie@israc.gov.il</a>
Head of Biology Chemistry & GLP	Etty Feller	M.Sc	03-5751690(202)	<a href="mailto:ettyf@israc.gov.il">ettyf@israc.gov.il</a>
Head of Quality Assurance	Tina Engelhard	M.Phil	03-5751690(212)	<a href="mailto:tinae@israc.gov.il">tinae@israc.gov.il</a>
Head of Administration & Training	Irit Sides	B.Sc, MBA	03-5751690(206)	<a href="mailto:irits@israc.gov.il">irits@israc.gov.il</a>
Legal Advisor and Spokesperson	Revital Sossover	Advocate	03-5751690(209)	<a href="mailto:revitals@israc.gov.il">revitals@israc.gov.il</a>
Head of Development	Zahava Nezri	B.Sc	03-5751690(203)	<a href="mailto:zahavan@israc.gov.il">zahavan@israc.gov.il</a>
Computer System Administrator	Ilanit Broide	B.Sc	03-5751690(213)	<a href="mailto:ilanitb@israc.gov.il">ilanitb@israc.gov.il</a>
Senior Secretary	Ruthie Neeman		03-5751690(207)	<a href="mailto:ruthien@israc.gov.il">ruthien@israc.gov.il</a>
Secretary	Tamar Bar		03-5751690(200)	<a href="mailto:tamarb@israc.gov.il">tamarb@israc.gov.il</a>
Secretary	Ortal Shiro		03-5751690(201)	<a href="mailto:ortals@israc.gov.il">ortals@israc.gov.il</a>



**D**uring the past year we focused on the following goals:

- 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 dust, 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.

**In 2002 we accomplished most of the tasks we set for ourselves:**

- The European market recognized the GLP recognized research facilities in Israel. ISRAC was invited to participate in the GLP committee of the OECD. ISRAC has signed an agreement of understanding with the EPA on GLP recognition. The agreement of understanding will be converted in mutual recognition after an assessment in Israel by a representative of the EPA. The agreement of understanding stipulates that the evaluation shall be held in the course of 2003. We hope that the security situation will not prevent the EPA representatives from visiting Israel.
- A small team was appointed to examine the possibility of changing ISRAC's surveillance system. To this end surveillance systems of comparable foreign organizations were studied, and the international standard ISO/IEC Guide 58 was examined, as well as the new standard ISO/IEC 17011 that is going to replace the former. The ILAC training and requirements manual was studied and conclusions were drawn from ISRAC's last years of operation. Based on the studied material it was decided that it was possible to reduce the surveillance audits of accredited laboratories by approximately 20%

on average. Accordingly, 3-year accreditation terms were established. Accreditation assessments shall include all accredited laboratory technologies and be performed by a team of professional auditors. In the period between two accreditations, surveillance assessments of a more limited nature shall be carried out, including the quality system and the way it supports each of the accredited laboratory technologies.

- ISRAC constantly scrutinized its procedures and operations and even conducted, during the summer and fall of 2002, a customer satisfaction poll, including the usefulness of the accreditation in the customers' eyes. Does this investment yield good results? To what extent does the accreditation contribute to the improvement of the laboratories' functional and business performance?

**Following are some general findings that emerged from conversations with laboratory managers:**

- Laboratory workers viewed accreditation as a professional achievement, not as a commercial necessity.
- Some of the laboratories operate on a competitive basis. In the construction and environmental fields the competitive-commercial benefit accompanying the accreditation was evident. In other competitive fields, laboratories did not give clear evidence of a competitive advantage as a result of accreditation.
- The managers and workers of the accredited laboratories perceived ISRAC as a superior professional body and they expect it to give expert answers to professional questions. In particular, the laboratories expect the assessors to be of the highest professional level.

**Main advantages as apparent from the poll:**

- A change for the better was found in almost every parameter that was measured. Laboratory managers are especially pleased with improved professional and skill levels of the workers, with measurement procedures that are planned and executed more accurately, reliably and effectively, and with better-calibrated equipment and improved documentation.
- The systematic investigation of faults and complaints was much improved in laboratories that managed to incorporate the standard's principles and to implement them operationally.



In these laboratories we usually observe a strong effect of learning, which is confirmed by internal and external reports.

- The laboratories are grateful for the assessors' feedback on state-of-the-art methods and equipment.
- Much appreciated are also the obligatory comparative inter-laboratory tests, which are very helpful for the laboratories.
- There was a better understanding of the customers' needs and requirements (including speed of response, reliability of tests and results, and form and content of reporting) and participation of the customer in decisions about operational methods.

**In view of the above it is not surprising that the laboratories report that the customers are increasingly satisfied.**

- In 2002 all GLP recognized laboratories were re-inspected (5 laboratories up to the end of 2002). The surveillances included completeness of knowledge and laboratory quality systems examinations. Five laboratories successfully completed the surveillances, carried out the necessary corrections and received renewed recognition.
- The accredited laboratories successfully completed adjustment to standard ISO/IEC 17025. Subjects changed with respect to ISO/IEC Guide 25 were: sampling, contract review, validation of test methods, consistency, uncertainty and opinions and interpretations. Activities in 2002 were centered on these subjects. Uncertainty estimations and especially explaining this issue to laboratory customers constituted a challenge to both ISRAC and the laboratories. ISRAC organized workshops and initiate contacts with the laboratories' customers and different regulators to explain the subject and learn the difficulties surrounding it.
- In 2002 ISRAC granted accreditation to the first medical laboratory. It is the central Magen David laboratory in Tel HaShomer, under the management of Prof. Eilat Shenhar. In addition, for the first time a laboratory was accredited to test air analysis and pressure vessels. Following a decision of ISRAC's Council and in accordance with the requirements of the authority

for public electricity service, ISRAC decided to enter the field of electricity testing in accordance with the policy and procedures of ISRAC.

A course on ISO/IEC 17025 was held for electrical engineers. Two of the electrical engineers participated in a course for training of professional assessors of ISRAC. At a later stage a committee will be established to advise ISRAC's general director on the materialization of the specific requirements for electricity testers.

- ISRAC invested several months of work in a project to create uniform accreditation scope documents. During the work on the uniform formulation of methods, products and standards we discovered more than once inaccurate formulations, misunderstandings between ISRAC and laboratories, etc. The reformulation was carried out with full cooperation of the laboratories, facilitating the work for laboratories requesting accreditation for specific tests. It will also make it easier for the laboratories' customers to understand and compare the laboratory's scope of accreditations.
- ISRAC's website was upgraded in 2002. The site is user-friendly and updated in Hebrew and English. A lot of information has been added and it now contains links to other accreditation bodies and organizations with which ISRAC maintains contacts and cooperates. We added FAQ's, articles and lectures on metrological subjects. ISRAC's quality manual and policy guidelines can also be found on the website.
- ISRAC deepened its relationship with the different regulators in Israel, especially with most divisions of the Ministry of Environment. As a result the office's industrial waste and fuel divisions issued instructions requiring the testing of fuel tanks by accredited laboratories. The office published a similar document concerning testing of air and hazardous dust.
- The advisory committee on construction developed a plan that hopefully will put in order the country's construction laboratories. According to this plan the project planner will provide a program stipulating what to test, which tests to apply, etc. No laboratory will be allowed to accept a project not including such a program. This plan is not meant to be a solution for all problems in the construction field, but it may improve things



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considerably. All relevant government offices, laboratories, contractors, local authorities and ISRAC participate in the plan. It was also presented to Judge Zeiler, who was appointed following the Versailles disaster. The chairperson of the professional committee, Dr. Mony Ben Bassat and the head of ISRAC's engineering department, Mr. Zvi Edelstain presented the plan to the Ministry of Interior. We hope that it will be accepted and that instructions will be issued accordingly.

In parallel we turned to the Ministry of Housing, one of the country's main enterprisers, which adopted a policy of ordering tests from the laboratory instead of from the project contractor. The same is true for the Ministry of Defense and the Public Works Department (Ma'atz). This change will hopefully improve the quality of construction in Israel.

- ISRAC's training program in 2002:
  - **Assessors training courses**
    - Assessors training course (February 02)
    - Medical laboratory assessors training course (March 02)
    - Assessors training course (December 02)
  - **Towards accreditation schemes**
    - Towards accreditation- comprehensive preparatory course (July 02)
    - Laboratory internal auditing (May 02)

### **Testing laboratories courses**

- Internal calibration in testing laboratories - comprehensive course (June 02)
- Validation of testing methods (October 02)
- Quality control of test methods in engineering laboratories (December 02)
- Quality control of analytical test methods (December 02)

### **Calibration laboratories courses**

- Matters concerning calibration laboratories (April 02)
- Matters concerning calibration laboratories – continuation (June 02)

### **Courses for laboratory customers**

- Advantages in communicating with accredited laboratories (June 02)
- Seminar for customers of calibration laboratories (December 02)

### **Assessors and consultants training activities**

- Assessors meeting (January 02)
- ISRAC's procedures internalization (July 02)
- Assessors and consultants training (October 02)

### **Training activities in cooperation with other bodies**

- GLP course in cooperation with the Signet Company (March 02)
- Testing and calibration laboratories accreditation requirements according to ISO/IEC 17025 in cooperation with the Standards Institution of Israel (February 02)



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### Main Activities Planned for 2003



- Deepening the awareness of ISRAC's activities among regulators and users of laboratory services.
- Development of new accreditation areas: electricity tests, electronic signature, etc.
- Providing information and training in areas related to laboratory quality management.
- Introduction of a new program at ISRAC for the management and monitoring of accreditation and surveillance operations.
- Implementation of the new surveillance system.
- Implementation and evaluation of the new pricing method.
- Widening the number of accredited medical laboratories.
- Intensifying ISRAC's international relations.



## Budget for 2002 and 2003

	2002 budget	2003 budget	Nominal Change
	NIS 000's	NIS 000's	%
<b>Expenditure</b>			
Regular operations	3,323.1	2,895.0	-12.9
Development	3,098.9	3,533.0	14.0
<b>Total Expenditure</b>	<b>6,422.0</b>	<b>6,428.0</b>	<b>0.1</b>
<b>Income from Operations</b>			
Accreditation and surveillance	1,777.0	2,025.0	14.4
Training and GLP inspections	275.0	280.0	1.8
<b>Total Income from Operations</b>	<b>2,045.0</b>	<b>2,305.0</b>	<b>12.7</b>
<b>Income from Funding</b>			
Funding of development - State budget	3,098.9	3,533.0	14.0
Regular funding - State budget	1,278.1	590.0	-53.8
<b>Total Income from Funding</b>	<b>4,377.0</b>	<b>4,123.0</b>	<b>-5.8</b>
<b>Total Income</b>	<b>6,422.0</b>	<b>6,428.0</b>	<b>0.1</b>

## Expenditure

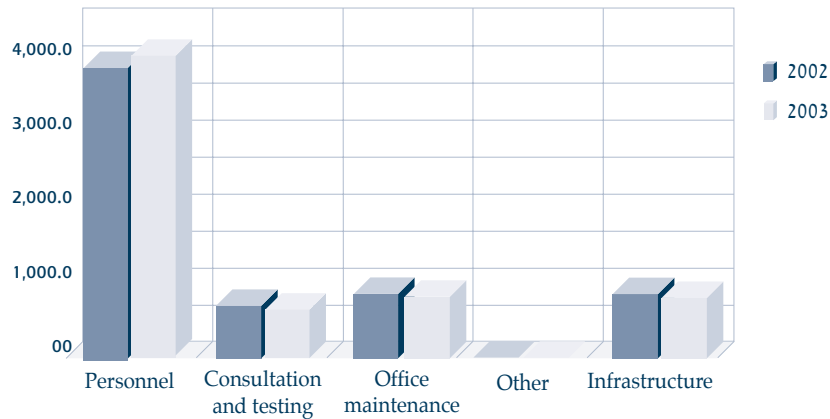
		2002 budget	2003 budget	Nominal Change
		NIS 000's	NIS 000's	%
<b>Expenditure</b>				
1.0	Personnel	3,900.0	4,111.0	5.4
2.0	Consultation and testing	706.0	672.0	-4.8
3.0	Office maintenance	885.0	830.0	-6.2
4.0	Other	10.0	5.0	-50.0
	<b>Total operating expenditure</b>	<b>5,501.0</b>	<b>5,618.0</b>	<b>2.1</b>
	Development element	-2,177.9	-2,723.0	25.0
	<b>Total regular operations</b>	<b>3,323.1</b>	<b>2,895.0</b>	<b>-12.9</b>
5.0	Infrastructure	921.0	810.0	-12.1
	Development components	2,177.9	2,723.0	25.0
	<b>Total development</b>	<b>3,098.9</b>	<b>3,533.0</b>	<b>14.0</b>
	<b>Total</b>	<b>6,422.0</b>	<b>6,428.0</b>	<b>0.1</b>



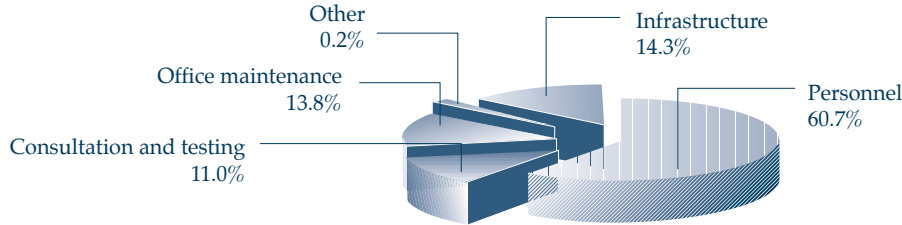
# Annual Report 2002



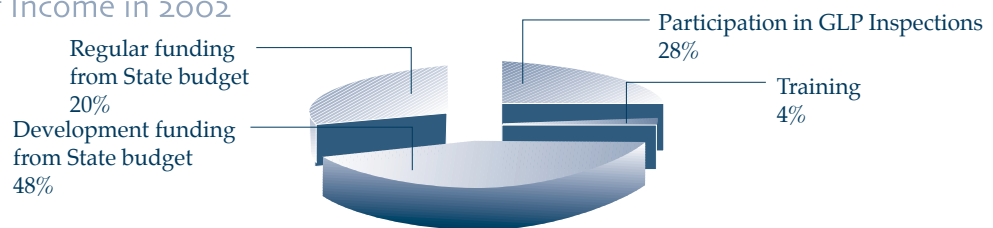
## Forecast of Expenditure in the 2003 Budget in Comparison to the 2002 Budget:



## Breakdown of Expenditure in 2002

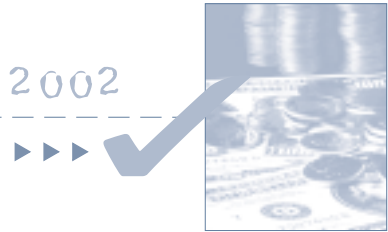


## Breakdown of Income in 2002

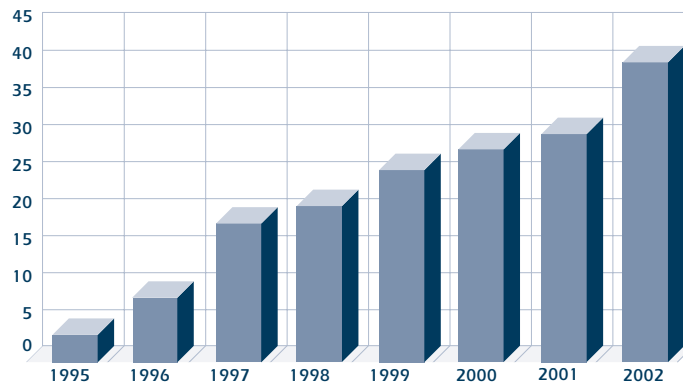


As of January 2003, 40 laboratories have received accreditation, and 5 research facilities received recognition to GLP. 36 laboratories are in the process of accreditation and 2 research facilities in the process of recognition.

Department	No. of accredited labs.	No. of labs. In the process of accreditation
Engineering	12	5
Biology & Chemistry	16	28
Calibration	12	3
GLP	5	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 2002, 29 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](http://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).

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 2,300 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.