



הרשות הלאומית להסמכת מעבדות Israel Laboratory Accreditation Authority

רח' כנרת קרית שדה התעופה, ת.ד. 89, לוד נמל תעופה 7015002 טל': 03-9702727 פקס: 03-9702413,
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National Laboratory Accreditation Authority Law

INTRODUCTION

We here present the English translation of the National Laboratory Accreditation Authority Law 5757-1997, which was passed by the Knesset on April 2, 1997, and appeared in Sefer-Ha-Chukkim of 5757, page 156.

- This is not an official translation –



NATIONAL LABORATORY ACCREDITATION AUTHORITY LAW 5757-1997

Definitions

1. In this Law –

- “tests” – including measurements and calibrations;
- “Council” – the Authority Council, as said in section 8;
- “Director” – The authority’s Director General, appointed under section 13;
- “accreditation” – recognition by the Authority of a laboratory’s ability and professional competence to perform tests in conformity with standards, regulations, specifications or other reference documents.
- “Authority” – the National Laboratory Accreditation Authority, set up under this Law;
- “Chairman of the Board” – the Chairman of the Board according to section 9;
- “laboratory” – including a testing, calibrating or measuring organization, which engages in laboratory work;
- “Minister” – the Minister of Industry and Trade.

Establishment of the Authority

2. The National Laboratory Accreditation Authority is hereby established.

The Authority – a body corporate

3. The Authority is a body corporate.

The Authority – an audited body

4. The Authority is an audited body, within the meaning of the term in section 9(2) of the State Comptroller Law 5718-1958 (consolidated Version).

The Authority’s responsibilities and powers

5. The Authority’s responsibilities and powers are as follows:

- (1) to determine – with approval by the Minister – the fields and types of tests, in respect of which laboratories shall be given accreditation;
- (2) to set requirements for the education and professional training of employees and managers of laboratories that apply for accreditation, and for the performance of tests and of test equipment;



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- (3) To grant applicant laboratories accreditation for fields and types of tests determined by it, and to set requirements for the grant of accreditation and conditions for its maintenance.
- (4) to serve as the State's only representative on any matter that pertains to its responsibilities, including the mutual recognition of accreditation authorities of other countries or of international organizations;
- (5) to cancel the accreditation of a laboratory, if it concludes – after the laboratory was given an opportunity to present its arguments – that it does not meet the requirements set for granting accreditation;
- (6) to initiate any activity that is connected with or part of the accreditation of laboratories that perform tests, including training, publicity and information;
- (7) to perform and to direct all activities necessary for the performance of its responsibilities under this section;

Transitional period and publication

6. When the Authority has determined a field or type of tests, in respect of which it will grant accreditation, then it shall – with approval by the Minister – set a transitional period until its determinations will go into effect, and it shall make tem public in Reshumot.

Conditions for approval of a laboratory under an enactment

7.
 - (a) If any enactment requires the approval, accreditation or recognition (hereafter: approval) of a laboratory that performs tests in fields and types of tests that were determined and made public as said in section 6 and for which the Authority granted accreditation, then a new approval shall be granted and the effect of an approval shall be extended only to a laboratory that was granted accreditation by the Authority under this Law.
 - (b) The provisions of subsection (a) shall only apply if the Minister in charge of the person authorized to give the approval consented to what is prescribed in section 5(1); aforesaid consent may be given retroactively.
 - (c) The provisions of this section shall not derogate from the powers of any person authorized to give approval and to set requirements for approval, in addition to shoes of the authority.

The Council

8.
 - (a) The Authority shall have a Council, consisting of seven members appointed by the Minister, as follows:
 - (1) a representative of the recognized institutions of higher education, within the meaning of that term in the Council of Higher Education Law 5718-1956 (hereafter: recognized institutions of higher education), who is educated in the field of the natural sciences or of technology and who was



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recommended by the Council of Higher Education, within its meaning in that Law, from a list submitted to it by the recognized institutions;

- (2) a representative of the organization that represents the largest number of engineers and architects registered in the Engineers and Architects Register, as defined in the Engineers and Architects Law 5718-1958;
 - (3) a representative of the laboratories accredited by the Authority, who shall be elected by a majority of the laboratories' managers or – in the absence of said elections – chosen by the Minister;
 - (4) a representative of users of laboratory services, recommended by the Coordinating Office of Economic Organizations after consultation with the New General Federation of Labor;
 - (5) the Commissioner of Standards in the Ministry of Industry and Trade;
 - (6) a representative recommended by the Minister of Science from among the staff of his Ministry, who shall have an education in the field of natural science or of technology;
 - (7) a representative recommended by the Minister of Finance from among the staff of his Ministry.
- (b)
- (1) The representative said in subsection (a)(1) shall not be a person employed by a body or body corporate that operates laboratories accredited by the Authority;
 - (2) the representatives said in paragraphs (a)(1) to (4) shall not be State employees;
 - (3) the representatives said in paragraphs (a)(6) and (7) shall be of the gender, which at that time is not appropriately represented on the entire Council.

Chairman of the Council

9.

- (a) The representative said in section 8(a)(1) shall be the Chairman of the Council and he shall also be the Chairman of the Authority.
- (b) The Minister shall appoint a permanent deputy of the chairman of the Council from among the Council members who are not State employees.

Responsibilities of the Council

10. The responsibilities of the Council are:

- (1) to prescribe the procedures and rules which will guide the Authority's activity and decisions, in line with the requirements derived from the international criteria and standards that regulate the activities of laboratory accreditation authorities



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- (2) to determine the fields of accreditation said in section 5(1), as well as the rules, criteria and international standards, according to which the Authority shall operate, including periods of accreditation of different types of laboratories;
- (3) to approve the Authority's budget, as said in section 27;
- (4) to supervise implementation of the Authority's policies.

Council meetings

11.

- (a) Meetings of the Council shall be held at least twice a year; the Chairman of the Council or three of its members may demand that a Council meeting be called.
- (b) The Chairman of the Council shall call the meeting demanded by Council members, as said in subsection (a), within 21 days after the demand.

Order of meetings

12.

- (a)
 - (1) Four members, including the chairman of the Council or his deputy, shall constitute a quorum at Council meetings;
 - (2) if a quorum is present when a meeting begins, then the continuation of the meeting shall be lawful with any number of members present, provided that at least three members – including the chairman of the Council or his deputy – are present when decisions are adopted;
 - (3) if no quorum is present when a council meeting is opened, then the Chairman of the Council may postpone it for half an hour; when the said half hour has passed, then the meeting shall be lawful with any number of members present, but the provisions of paragraph (2) shall apply to the adoption of decisions.
- (b) Council decisions shall be adopted by a majority of Council members participating in the vote; in case of a tie vote the chairman shall decide and – in his absence – his deputy.
- (c) The council shall prescribe its procedures, to the extent that those were not prescribed in the Law or in regulations.

Appointment of Director and his responsibilities

13.

- (a) The Council shall – with approval by the Minister – appoint a Director General for the Authority.



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- (b) A person convicted of an offense which – in the Attorney General's opinion – bears an element of disgrace, or a person indicted for a said offense shall not be appointed Director General.
- (c) The Director is in charge of the performance of the Authority's responsibilities and of the implementation of the Council's decisions.

Director's term of office

14.

- (a) The Director's term of office shall be four years; the Council may – with approval by the Minister – reappoint him for additional terms of office.
- (b) The Director shall cease to serve before the end of his term of office when any one of the following occurs:
 - (1) he resigned by delivering a letter of resignation to the Minister and to the Chairman of the Council;
 - (2) the Council decided – by a majority of its members, at least one of them a State employee – to terminate his term of office;
 - (3) he was indicted for an offense which – in the Attorney General's opinion – bears an element of disgrace.
- (c) If the Director is temporarily unable to meet his responsibilities, then the Council shall – with approval by the Minister – appoint a Deputy Director; if the Director's place fell vacant and another has not yet been appointed in his place, then the council may appoint an Acting Director for a period of not more than 30 days.

Director's terms of employment

15. The Minister shall, in consultation with the Minister of Finance, determine the pay and terms of employment of the Director.

Advisory committee

16.

- (a) The Minister shall appoint an Advisory committee to the Council and to the Director, consisting of 30 members as follows:
 - (1) Thirteen representative of the Government recommended by each of the following Ministers from among ranking staff of his Ministry:
 - (a) the Minister of the Environment;
 - (b) the Minister of Defense;
 - (c) the Minister of Construction and Housing;
 - (d) the Minister of Health;
 - (e) the Minister of Foreign Affairs;
 - (f) the Minister of Agriculture;
 - (g) the Minister of Science;



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- (h) the Minister of Labor and social welfare;
 - (i) the Minister of the Interior;
 - (j) the minister of Transportation;
 - (k) the Minister of Industry and Trade;
 - (l) the Minister of Communications;
 - (m) the Minister of National Infrastructures
- (2) a ranking representative of the Israel Police;
- (3) a ranking representative of the Israel Defense Forces;
- (4) 15 representatives of the public, as follows:
- (a) two representatives recommended by the Israel Standards Institute, from among its staff;
 - (b) two representatives recommended by the Agricultural workers Union – Agricultural Center;
 - (c) one representative of consumer organizations, within the meaning of that term in the consumer Protection Law 5741-1981' from a list submitted by the consumer organizations;
 - (d) three representatives recommended by the Coordinating Office of Economic Organizations;
 - (e) three representatives of the recognized institutions of higher education who engage in research, from a list submitted by the recognized institutions;
 - (f) four additional representatives of the public.
- (b) The Minister shall appoint the Chairman of the Advisory Committee and his deputy from among the members of the Committee.
- (c) At least half of all members of the Advisory Committee shall be women.

Responsibilities of Advisory Committee

17.

- (a) The Advisory Committee may advise the Council on anything that pertains to the determination of fields of accreditation and of international standards, according to which the Authority shall operate.
- (b) The Advisory committee may advise the Council and the Director, at their request and application, on any other matter connected with the Authority's responsibilities, as specified in section 5.
- (c) The Advisory Committee may appoint subcommittees – either permanent or for a specific matter, as the need may be – from among Committee members and others.



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Term of office

18. Members of the Council and of the Advisory Committee shall be appointed for three years, and they may be reappointed for one additional term; the provisions of section 13(b) shall apply to their appointment.

End of term

19. A member of the Council or of the Advisory Committee shall cease to serve before the end of his term in office when one of the following occurs:

- (1) he resigned by delivering a letter of resignation to the Minister;
- (2) he was indicted for an offense which – in the Attorney General's opinion – bears an element of disgrace;
- (3) he ceased being an employee of the Government Ministry or of the body which he represents on the Council or on the Advisory Committee;
- (4) in respect of a representative of the public – he became a State employee.

Removal from office

20. The Minister may remove a member of the council or of the Advisory Committee from office before the end of his term of office, if he is permanently unable to meet his responsibilities.

Effect of acts

21. The existence of the council and of the Advisory Committee, their powers and their decisions shall not be affected adversely because the place of a member of the council or of the Advisory Committee fell vacant, or because of any fault in his appointment or of the continuation of his term of office.

Conflict of interests

22.

- (a) A member of the Council or of the Advisory Committee shall refrain from participating in the discussion and from voting at Council or Advisory Committee meetings, if the subject under consideration is liable to place him – directly or indirectly – in a conflict of interests between his responsibility as Council or Advisory Committee member and his own personal interests or some other responsibility of his, other than a responsibility which he bears in the body that he represents on the council or the Advisory Committee; a member of the Council or of the Advisory Committee also shall not – within the framework of his responsibilities in the Authority – deal with an aforesaid matter outside Council or Advisory Committee meetings.
- (b) When a member of the Council or of the Advisory Committee learns that the subject under consideration is liable to place him in a conflict of interests as said in subsection (a), then he shall so inform the Chairman of the council or of the Advisory Committee.



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(c) For purposes of this section –

- (1) it is irrelevant whether or not he bears the other responsibility for consideration;
- (2) “personal interest” includes the personal interest of his relative or of a body, in which the member of the Council or of the Advisory Committee or his relative is a controlling member;

“relative” – spouse, parent, parent’s parent, sibling, offspring, a spouse’s offspring and the spouses of any of these, or any other dependent of the member of the Council or of the Advisory Committee, as well as an agent, partner, employer or employee of the aforesaid member;

“Controlling member” – manager, responsible employee or a person who has a part larger than 5% of the capital or of the profits of an aforesaid body.

Terms of employment of Authority employees

23.

- (a) The Director shall – with approval by the Council and after having received approval from the Minister and the Minister of Finance – determine the list of positions in the Authority and the pay and terms of employment for them.
- (b) When an employee is hired for a position with the Authority, then the Director shall determine his terms of employment, his pay and the period of his employment within the framework of pay and terms of employment determined in accordance with this section.

Remuneration

24.

- (a) Members of the Council or of the Advisory Committee shall not receive any pay from the Authority for their services.
- (b) Members of the Council shall be entitled to remuneration for their participation in Council meetings, at rates and according to rules to be prescribed by the Minister in consultation with the Minister of Finance.

State of Authority employees and of Council members

25.

- (a) For purposes of the following enactments Authority employees shall be treated like State employees:
 - (1) the Knesset and Prime Minister Elections Law (Consolidated Version) 5729-1969;
 - (2) the Public Service (Restrictions on Political Party Activity and Fundraising) Law 5719-1959;
 - (3) the Public Service (Gifts) Law 5740-1979;



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- (4) the Public Service (Restrictions After Retirement) Law 5729-1969;
 - (5) the Evidence Ordinance (New Version) 5731-1971;
 - (6) the Civil Wrongs Ordinance (New Version);
 - (7) the Penal Law 5737-1977 – the provisions that relate to public servants.
- (b) Members of the Council who are not State employees shall be treated like State employees for purposes of the enactments said in subsection (a)(2), (3), (6) and (7).

Confidentiality

26.

- (a) No person shall reveal any information or the contents of any document that reached him by virtue of his responsibility under this Law, except by demand of a Court, of the Attorney General or for purposes of a lawful investigation.
- (b) If a person violates provisions of subsection (a), then he shall be liable to one year imprisonment.

Budget and finances

27.

- (a) Every year, at a time to be set by the Council, the Director shall prepare the Authority's ordinary budget and development budget for the coming fiscal year; the budget must be approved by the authority, by the Minister and by the Minister of Finance.
- (b) The Authority's development budget shall be financed by the State Treasury within the framework of the Budget Law, and its ordinary budget shall be financed by income, fees and payments which it shall collect for its services.
- (c) Notwithstanding the provisions of subsection (b), the Minister of Finance may approve participations from the State budget in the Authority's ordinary budget.

Annual report

28. The Director shall prepare an annual report of the authority's activity, and he shall submit it to the Minister after its approval by the Council.

Right of Access

29. The Authority shall make it possible for all persons to peruse – in a place and at times which it shall determine and make public – the rules, criteria and standards according to which it operates.

Status of Authority

30. The Authority shall be treated like the State for purposes of taxes, stamp duty, fees, rates, levies and other mandatory payments.



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Status of State

31. For purposes of the provisions of this Law, the State and its institutions shall be treated like any other person.

Implementation and regulations

32. The Minister is charged with the implementation of this Law and he may make regulations for its implementation, and that includes regulating the procedure of accreditation and the right to apply for an additional hearing on a decision that relates to the accreditation of a laboratory.

Fees

33. The Minister is allowed to define with the approval of the Minister of Finance and the Economic Committee in parliament, fees and general rules for payments for ISIRAC activities as mentioned in section 5 to this law.

Transfer of funds allocated by the Budget Law

34. The Government shall transfer to the Authority all the amounts budgeted in the Budget Law for the current fiscal year for those laboratory accreditation activities, the implementation of which is transferred to the authority and which were not expended by the day on which this Law went into effect; for this purpose; "current fiscal year" – the fiscal year in which falls the day on which this Law goes into effect.

Transitional provision

35. The Minister shall choose the representative of the laboratories, who shall be appointed by him as member of the Council for a period of two years after the day on which this Law went into effect, instead of the representative said in section 8(a)(3).



References

The law here translated and the enactments mentioned in it are listed below with their various references. Wherever possible we refer readers to English language versions, both those published by the Ministry of Justice in its Laws of the State of Israel yearbooks, and the consolidated law translations produced by Aryeh Greenfield – A.G. Publications.

The following abbreviations have been used in this table of references, as well as elsewhere in these pages:

AG Aryeh Greenfield – A.G. Publications

LSI Laws of the State of Israel (translated)

NV Laws of the State of Israel – New Version (translated)

SH Safer Ha-Chukkim (Hebrew original)

Consumer Protection Law 574101981 – AG, 1996

Council of Higher Education Law 5718-1956 – LSI XII, p.217

Engineers and Architects Law 5718-1958 – LSI XX, p.124

National Laboratory Accreditation Authority Law 5758-1997 – SH of 5757,
p.156

Knesset and Prime Minister Elections Law (Consolidated Version) 5729-
1969 – LSI XXIII, p. 110

Public Service Law (Restrictions on Political Party Activity and fundraising)
Law 5719-1959 – LSI XIII, p.203

Public Service (Gifts) Law 5740-1979 – LSI XXXIV, p.3

Public Service (Restrictions After Retirement) Law 5729-1969 – LSI XXIII,
p.156

Evidence Ordinance (New Version) 5731-1971 – NV II, p.198

Civil Wrongs ordinance (New Version) - NV II, p.5

Penal Law 5737-1977 – AG, 1994

State Comptroller Law 5718-1958 (Consolidated Version) – LSI XII, p.107



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A notification on Laboratory Accreditation Field Declaration

Following Israel Laboratory Accreditation Authority law -1997

I hereby declare by the power of article 5(1) to the law of Israel Laboratory Accreditation Authority- 1997¹ and with economy minister authorization, Israel Laboratory Accreditation Authority states GLP testing as accreditation field.

May 16th, 1999

(3-2866 signature's number)

Shlomo Grossman
ISRAC's chairman

¹ 68 1997, page 156