

Patent Cooperation Treaty (PCT)

Common Quality Framework for International Search and Preliminary Examination

ANNUAL REPORT ON QUALITY MANAGEMENT SYSTEMS

prepared by The ISRAEL PATENT OFFICE (ILPO)

The Authority should provide general background information relevant to the quality management system (QMS) as set forth in this template.

The descriptions below each main heading of this template should be considered examples of the type and arrangement of information that should be included under each heading. Each Authority may provide additional information beyond that set forth in this template as desired.

INTRODUCTION (PARAGRAPHS 21.01 - 21.03)

In this introduction, each Authority should include a summary of all changes to their quality management system that have taken place since the previous report on their Quality Management System, and any other matters considered to be interest in relation to quality management.

If applicable, the Authority may at this point indicate any recognized normative reference or basis for their quality management system besides Chapter 21, such as ISO 9001, under the heading "Normative Reference for QMS"

For example: "Normative reference for QMS: ISO 9001, EQS (European Quality System)"

Each Authority should then provide at least the information indicated in the descriptive boxes, under the following headings. Authorities may include process charts if this would facilitate the understanding of an aspect of the report.

Summary of the ILPO activities, changes and events in 2018

• Recruitments at the ILPO

- Two new team managers, in the fields of physics and mechanics & electronics, have been appointed, thus reaching a total number of 13 team managers in 7 different technical fields.
- Ten new patent examiners have been recruited to the ILPO and have started their 2-year training program which has been recently upgraded.

• Upgraded automated system

The internal automated system for processing national applications has been upgraded to improve the work environment (including, *inter alia*, standardized clauses), extend the documentation scope of structured data (including, *inter alia*, citations and CPC codes) and include quality assurance procedures. The new internal system is fully operative and is currently used by ILPO staff.

• Improving the mechanism for allocation of patent applications

An automated allocation mechanism in the internal systems has been developed to improve the task allocation efficiency for all the substantive examiners.

• Evaluation of AI-based search

A pilot study has taken place with 3 different companies to evaluate the possibility of implementing an AI-based prior art search.

• Service level agreement

The service level agreement has been extended to address each technical field separately.

• Meetings with IP representatives

Two round table meetings with patent attorneys took place at the ILPO concerning the substantive examination in different technical fields. The first meeting was held in the fields of pharmaceuticals and chemistry and the second meeting in the fields of mechanics and medical devices. Another round table meeting will take place in December 2018 in the field of computers and telecommunications.

• Meeting with Israeli IP professional associations

A meeting with Israeli IP professional associations was held in January 2018.

• Updating Examination Guidelines

The Examination Guidelines for the formalities and substantive examination has been updated.

- The main changes in the substantive Examination Guidelines, which were published in December 2017, relate to aspects in the examination of novelty (second use, inherency, pharmacokinetic parameters, synergism, product by process and ranges) and examination of amendments in the specification.
- During 2018, new substantive Examination Guidelines have been prepared concerning the examination of novelty (biological mechanism and pharmaceutical compositions intended for specific populations); inventive step (pharmacokinetic parameters, interactions between components); inventions related to varieties of plants and animals; priority validity; and result to be achieved.
- In order to reduce the examination period for national patent applications, a new policy has been implemented according to which the number of Office Actions

sent to the applicant has been limited to 3, after which a Notice before Final Rejection is sent.

- **Extended teleworking**

Following amendments to the Teleworking Regulations:

- The teleworking project has been extended to include also PCT formalities examiners, in addition to the existing substantive examiners.
- The number of substantive examiners joining the teleworking project has increased to 40%.

- **Visits to industrial firms**

- In December 2017, a study visit was made by 14 ILPO examiners to Bio-Technology General Israel – BTG in Kiryat Malachi. The visit included a tour in the company's manufacturing facility as well as lectures and explanations about the products of the company, the economic model on which the company's activity is based and IP-related aspects.
- In November 2018, a study visit was made by 20 examiners to IBM Research – Haifa. The study included lectures and explanations about the company's contribution to innovation and its current and future computing and communication technologies; and discussions about IP-related aspects.

- **Courses at the ILPO**

- A second advanced mentoring course, in addition to the first course conducted in 2016, has been provided to senior examiners, including theoretical and practical aspects in teaching, evaluating and giving feedback. This course is intended to further enhance the training proficiency of senior examiners acting as personal mentors for the newly recruited patent examiners.
- A WIPO Academy Internship course in the fields of pharmaceuticals, chemistry and biology was held at the ILPO in October 2018.

- **Offshore training activities**

In June 2018, two ILPO examiners participated in CPC training at the EPO, The Hague, The Netherlands.

- **Payment netting pilot**

In order to reduce exposure of WIPO's fee income to movements in currency exchange rates and to improve the management of the transfer of PCT fees to the IB, the ILPO, in its capacity as an RO, joined the netting pilot.

- **Monitoring ILPO ISR citations' re-usage in national phase**

A method has been developed to monitor the re-usage of ISR publications cited by the ILPO in the national phase in other Offices for QA purposes.

- **Process chart**

A process chart has been included in the QMS Report, summarizing the procedures in the processing of PCT applications at the ISA and IPEA stages.

- **Statistical data**

The statistical data in the Annex to the QMS Report have been updated.

About the Israel Patent Office (ILPO)

The Israel Patent Office (ILPO) is part of the Ministry of Justice and has been operating, since 2006, as the first executive agency in Israel's Civil Service, which gave it independence in several fields. The ILPO is responsible for providing the public with the appropriate resources to achieve the registration of patents, designs, trademarks and appellations of origin, which provide adequate legal protection for industrial intellectual property in Israel. This is obtained by professional, efficient and high-standard substantive and formalities examination procedures.

The ILPO has been fully operative as an International Searching Authority (ISA) and an International Preliminary Examination Authority (IPEA) since June 1, 2012, following its appointment in October 2009. The services of the ILPO, in its capacity as an ISA/IPEA, were initially provided only to Israeli applicants and at a later stage also to US and Georgian applicants.

The ILPO, in its capacity as an ISA/IPEA, performs search and examination for all the technical fields to the most possible extent, including subject matter for which the ILPO is not required to perform search and examination under PCT Rules 39 and 67, such as methods for therapeutic treatment of the human body and methods of doing business.

The ILPO has signed PPH arrangements, including PCT-PPH, with a number of Patent Offices and joined GPPH to promote international work sharing and improve the quality of patent examination.

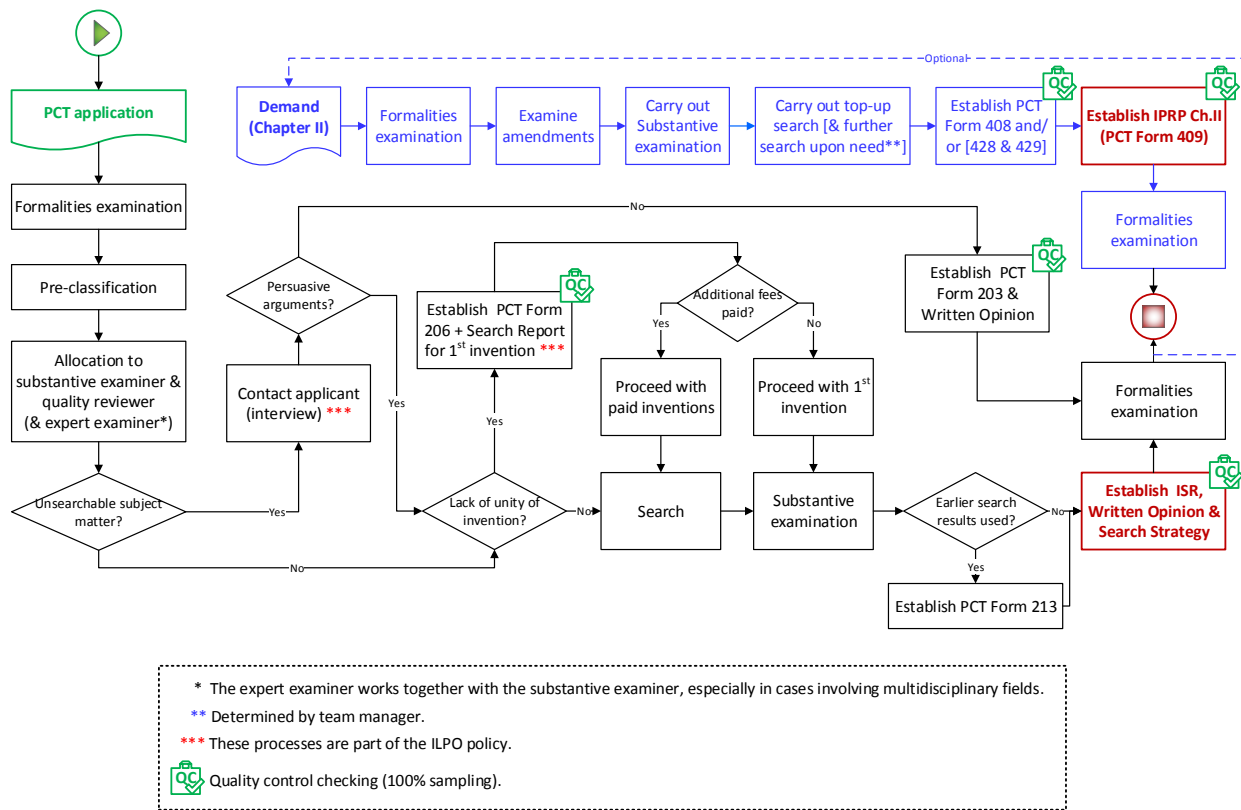
Following the EPO's implementation of the "PCT Direct" service in November 2014, and in a step to improve the efficiency and quality of the examination of PCT applications, the ILPO has launched the PCT Direct service in April 2015.

One of the accelerated examination routes for national applications, under Section 19A of the Israel Patents Law, relates to IL applications which are intended to serve as basis for claiming a right of priority, according to the Paris Convention or the PCT, based on a declaration made by the applicant. This route allows applicants to receive an Office Action and a National Search Report within 3 months from the date the application is approved for accelerated examination. These reports can be established in English upon applicant's request. For PCT applications claiming priority from these IL applications and selecting the ILPO as ISA, 50% of the paid search fee are refunded, provided that the search results of the IL applications are used in the ISRs of the PCT applications. Part of these IL applications serve as a basis for claiming a right of priority for PCT applications selecting ISA/IL and fulfilling the requirements of the "PCT Direct" service.

About the Quality Management System of the ILPO

The ILPO has a Quality Management System certified according to ISO 9001:2015 since January 2017, following its certification according to ISO 9001:2008 since 2010. The certification covers all services offered by the ILPO: processing of national patent applications, international applications under the Patent Cooperation Treaty (PCT), Industrial Designs and Trademarks. The ILPO's QMS is annually assessed by an independent certification body which conducts external audits. Due to the ILPO's certification to ISO 9001, the ILPO has taken measures towards instituting a quality framework for the processing of national and international applications, which meets the requirements of the Quality Framework set out in Chapter 21 of the PCT International Search and Preliminary Examination Guidelines.

The following chart summarizes the procedures in the processing of PCT applications at the ISA and IPEA stages:



1. LEADERSHIP AND POLICY

21.04 Confirm that the following are clearly documented, and that this documentation is available internally:

- The quality policy established by top management.
- The roles and names of those bodies and individuals responsible for the QMS, as specified by top management.
- An organizational chart showing all those bodies and individuals responsible for the QMS.

(a) The Quality Manual of the ILPO includes the quality policy, the bodies responsible for the QMS and an organizational chart showing all the bodies and individuals responsible for the QMS for all the departments of the ILPO. This manual is posted on the intranets of the ILPO departments.

The ILPO considers meeting strict quality criteria as the leverage and main means for ensuring the registration of patents, designs and trademarks that will provide appropriate legal protection for the intellectual property in Israel while preserving the legal rights of others within a fair balance. The ILPO considers the quality of its services as an essential component in enhancing efficiency and as a crucial factor in its integration into the

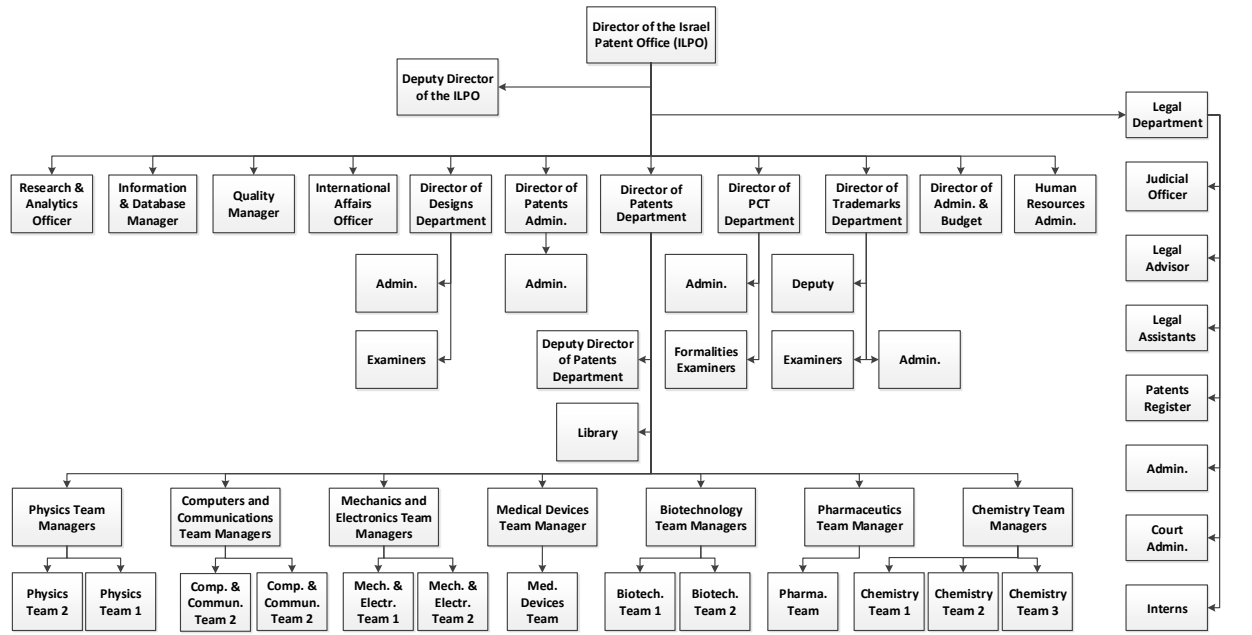
international community by international treaties that require compliance with high-level quality standards, including, *inter alia*, the Madrid Protocol and the PCT. Regarding the latter, the ILPO, in its capacity as an International Searching and Examining Authority, is committed to receiving and processing international patent applications according to the PCT Regulations, PCT Administrative Instructions, the PCT Receiving Office (RO) Guidelines, the PCT Search and Examination Guidelines and the internal instructions. The ILPO has a Quality Management System (QMS) certified according to ISO 9001:2015. The certification covers all services offered by the ILPO including, *inter alia*, the processing of national and international patent applications. The ILPO's QMS is annually assessed by an independent certification body which conducts external audits. The ILPO considers the users of ILPO services and the ILPO staff as the two main factors determining the success of its operation as a national and International Authority.

- (b) The ILPO's top management has appointed a Quality Manager, as defined in ISO 9001:2015, to take charge of the day-to-day implementation and continuous improvement of the quality management system. He reports on the functionality of the quality management system and provides recommendations to the top management regarding required measures for improvement.

The main functions of the Quality Manager are:

- planning, coordinating and implementing the quality policy;
- promoting and coordinating the preparation and updating of standards and procedures;
- promoting and coordinating certification of all activities of the ILPO according to ISO 9001;
- ensuring establishment and implementation of procedures for the Quality Management System (QMS) in accordance with the requirements of standards: ISO 9001:2015, PCT Regulations and the International Search and Preliminary Examination Guidelines (Chapter 21);
- developing, distributing, reviewing and updating Quality Manuals;
- performing controls to validate the implementation of quality policy;
- ensuring that deadlines and objectives are met;
- proposing, coordinating and supervising surveys among users;
- promoting standards and procedures and providing technical guidance to the units involved; and
- providing data for external audits.

(c) ILPO organizational chart



21.05 Indicate (e.g. by means of a table) the extent of compatibility between the Authority's QMS and the requirements of Chapter 21 of these International Search and Preliminary Examination Guidelines. Alternatively, indicate where the Authority is not yet compliant with these requirements.).

[Sample table, to be amended as necessary]

Chapter 21 requirement				Extent of compliance		
				full	part	no
21.04		(a)	Quality policy available	✓		
		(b)	Identified roles and names for QMS responsibility	✓		
		(c)	Organizational chart available	✓		
21.05			Established compatibility of QMS with Chapter 21	✓		
21.06		(a)	Mechanisms to ensure effectiveness of the QMS	✓		
		(b)	Control of the continual improvement process	✓		
21.07		(a)	Communication of management about this standard to staff	✓		
		(b)	The PCT Guidelines are in line with the Authority's QMS	✓		
21.08		(a)	Management reviews take place	✓		

Chapter 21 requirement			Extent of compliance		
			full	part	no
	(b)	Quality objectives are reviewed	✓		
	(c)	Communication of quality objectives to the relevant staff at the Authority	✓		
21.09	(a)	Performance of a yearly internal review of the QMS in/to	✓		
	(b)	determine the extent to which the QMS is aligned with Chapter 21	✓		
		determine the extent to which S&E complies with PCT Guidelines	✓		
	(c)	an objective and transparent way	✓		
	(d)	using input incl. information according paragraph 21.24	✓		
	(e)	recording the results	✓		
21.10		Assurance to monitor and adapt to actual workload	✓		
	(i)	Infrastructure in place to ensure that a quantity of staff	✓		
	(a)	sufficient to deal with the inflow of work	✓		
	(b)	which maintains technical qualifications to S&E in all technical fields	✓		
	(c)	which maintains the language facilities to understand languages according to Rule 34	✓		
	(ii)	Infrastructure to provide a quantity of skilled administrative staff	✓		
	(a)	at a level to support the technically qualified staff	✓		
	(b)	for the documentation records	✓		
	(iii)	Ensuring appropriate equipment to carry out S&E	✓		
	(iv)	Ensuring documentation according to Rule 34	✓		
	(v)	(a) Instructions to help staff understand and act according to the quality criteria and standards	✓		
		(b) Instructions to follow work procedures accurately and they are kept up-to-date.	✓		
	(vi)	(a) Training and development program to ensure and maintain necessary skills in search and examination	✓		
		(b) Training and development program to ensure awareness of staff to comply with the quality criteria and standards.	✓		
	(vii)	(a) System in place for monitoring resources required to deal with demand	✓		
		(b) System in place for monitoring resources required to comply with the quality standards in S&E	✓		

Chapter 21 requirement				Extent of compliance		
				full	part	no
21.11	(i)		Control mechanisms to ensure timely issue of S&E reports	✓		
	(ii)		Control mech. regarding fluctuations in demand and backlog	✓		
21.12	(i)		Internal quality assurance system for self-assessment	✓		
		(a)	for compliance with S&E Guidelines	✓		
		(b)	for channeling feedback to staff	✓		
	(ii)		System for measurement of data and reporting for continuous improvement	✓		
	(iii)		System for verifying the effectiveness of actions taken to correct deficient S&E work	✓		
21.14		(a)	Contact person helping identify best practice between Authorities	✓		
		(b)	Contact person fostering continual improvement	✓		
		(c)	Contact person providing for effective communication with other Authorities for feedback and evaluation	✓		
21.15	(i)	(a)	Appropriate system for handling complaints	✓		
		(b)	Appropriate system for taking preventive/corrective actions	✓		
		(c)	Appropriate system for offering feedback to users	✓		
	(ii)	(a)	A procedure for monitoring user satisfaction & perception	✓		
		(b)	A procedure for ensuring their legitimate needs and expectations are met	✓		
	(iii)		Clear and concise guidance on the S&E process for the user	✓		
			Indication where and how the Authority makes its quality objectives publicly available	✓		
21.16			Established communication with WIPO and designated and elected Offices	✓		
21.17			QMS of Authority clearly described and documented	✓		
21.18		(a)	Material making up the reference of quality procedures and processes for staff and management has been prepared and distributed	✓		
		(b)	Media available to support the reference material	✓		
		(c)	Document control measures are taken	✓		
21.19			Items which should be documented in the reference of quality procedures and processes	✓		
	(i)		Quality policy of the Authority and commitment to QMS	✓		
	(ii)		Scope of QMS	✓		
	(iii)		Organizational structure and responsibilities	✓		

Chapter 21 requirement			Extent of compliance		
			full	part	no
	(iv)	the documented processes are carried out in the Authority	✓		
	(v)	Resources available to carry out processes and implementing the procedures	✓		
	(vi)	a description of the interaction between the processes and the procedures of the QMS.	✓		
21.20	(i)	Records which documents are kept and where they are kept	✓		
	(ii)	Records of results of management review	✓		
	(iii)	Records about training, skills and experience of staff	✓		
	(iv)	Evidence of conformity of processes	✓		
	(v)	Results of reviews of requirements relating to products	✓		
	(vi)	Records of the S&E process carried out on each application	✓		
	(vii)	Record of data allowing individual work to be tracked	✓		
	(viii)	Record of QMS audits	✓		
	(ix)	Records on actions taken re. non-conforming products	✓		
	(x)	Records on actions taken re. corrective actions	✓		
	(xi)	Records on actions taken re. preventive actions	✓		
	(xii)	Records referring to search process documentation	✓		
21.21	(i)	Recording of the databases consulted during search	✓		
	(ii)	Recording of keywords, combination of words and truncations during search	✓		
	(iii)	Recording of the languages used during search	✓		
	(iv)	Recording of classes and combinations thereof consulted during search	✓		
	(v)	Recording of a listing of all search statements used in databases consulted	✓		
	(vi)	Records about other information relevant to the search	✓		
	(vii)	Records about limitation of search and its justification	✓		
	(viii)	Records about lack of clarity of the claims	✓		
	(ix)	Records about lack of unity	✓		
21.22		Report on its own internal review processes	✓		
21.23-21.25		Additional information on further inputs to its internal reviews	✓		
21.26		Initial report called for by paragraph 21.26	✓		

21.06 Indicate with reference to the organizational chart those bodies and mechanisms management uses to ensure:

- (a) the effectiveness of the QMS; and
- (b) that the process of continual improvement progresses.

(a) Effectiveness of the QMS

The effectiveness of the QMS is ensured by the Management that sets annual goals, including detailed quarterly tasks, in the last quarter of each previous year, from which the current as well as the new quality-related tasks are derived. The management also reviews the progress of the quality program, approves documents and discusses quality-related issues.

(b) Continual improvement progress

The Quality Manager ensures that the process of continual improvement progresses throughout the Office and reports directly to the Director of the ILPO in matters regarding quality of services and the QMS from the data available to him and from the feedback received from the directors of departments, team managers, examiners and customers.

When there is a need to change the examination guidelines of patent applications; due to a recommendation from the Quality Manager or directors of the Patents Department, feedback from users, or a change in legislation or practice; the Director of the ILPO assigns a task for the Examination Guidelines Team to amend the existing examination guidelines or, where appropriate, establish new guidelines. The updated draft of the examination guidelines is then made open to feedback from the examiners and also from the public. Following the feedback, the draft version may be amended. When the final version of the guidelines is approved, the ILPO staff and public are notified about the changes, by email and/or staff meetings, and training may be provided to the examiners upon need. The Improvement Team makes a follow-up of the new guidelines and provides feedback and suggestions.

A Quality Coordinator has been appointed for each department in the Office (Patents, Designs, Trademarks, PCT and Administration).

Team Managers for each technical field (computers and communications, mechanics, physics, medical devices, biotechnology, pharmaceuticals and chemistry) in the Patents Department is responsible for the quality checking of the national Office Actions and the international reports produced. The Team Managers have taken charge of collecting sampled data, in accordance with predetermined criteria, of the percentage of citations in the national/regional phase abroad which are derived from the ISRs of the ILPO.

Internal reviews take place at least once a year, in which the Quality Manager meets with an external quality consultant and receives feedback and support. These reviews are presented to top management at management reviews.

A Research & Analytics Officer has been appointed at the ILPO in November 2017, taking charge of initiation, implementation, promotion and presentation of research providing an added value to the ILPO and serving as a tool for its policy. The Research Officer also takes charge of cooperation in research with various parties in Israel and abroad.

Regular external surveillance audits are conducted by independent assessors to ensure continuous compliance with ISO 9001.

21.07 Indicate how management of the Authority communicates to its staff the importance of meeting treaty and regulatory requirements including:

- (a) those of this standard; and*
- (b) complying with the Authority's QMS.*

The ILPO communicates to staff the importance of quality-related issues by meetings, emails and documentation on the ILPO's intranet sites.

21.08 Indicate how and when top management of the Authority or delegated officers:

- (a) conducts management reviews and ensures the availability of appropriate resources;*
- (b) reviews quality objectives; and*
- (c) ensures that the quality objectives are communicated and understood by the relevant staff at the respective Authority.*

A Quality Management Review is held at least once a year according to the Quality Management Standards set out in ISO 9001:2015.

The Board of the ISA/IPEA has been established, including the directors of the Patents Department and PCT Department, deputy director of the Patents Department, ISA/IPEA IT coordinator of the PCT Department, quality manager of the ILPO and, the PCT quality coordinator. The main goal of the Board is to make sure that there is consistency in the output between the two departments. The Board resolves issues related to international work (ISA/IPEA) and monitors processes in operations, formalities and substantive examination. In addition, this forum monitors nonconformities arising from transactions between the different departments (Patents and PCT) in the Office. The Board of the ISA/IPEA also considers what changes, if any, should be made to the internal automated system (PCT SAPIA) as a whole. This Board meets regularly to discuss issues raised by the substantive patent examiners and PCT formalities examiners.

Furthermore, the ISA/IPEA IT coordinator regularly meets with the director of the PCT Department to discuss technical issues in the automated system (PCT-SAPIA) for processing international applications. A list of suggested improvements is then prepared and discussed at the Board meeting.

21.09 Indicate whether top management or delegated officers of the Authority perform an internal review of the QMS in accordance with paragraphs 21.22-21.25:

- (a) at least once per year (cf. paragraph 21.22);*
- (b) in accordance with the minimum scope of such reviews as set out in Section 8, namely:
to determine the extent to which the QMS is based on Chapter 21 (cf. paragraphs 21.22, 21.24(i));
to determine the extent to which Search and Examination work complies with PCT Guidelines (cf. paragraphs 21.22, 21.24(i));*
- (c) in an objective and transparent way (cf. paragraph 21.22);*
- (d) using input including information according to paragraphs 21.24 (ii)-(vi);*
- (e) recording the results (cf. paragraph 21.25).*

Executive meetings chaired by the Commissioner (ILPO Director) and attended by all department directors are regularly held. During these meetings QM issues are reviewed,

availability of appropriate resources is discussed and necessary steps are taken to ensure remedies as needed. Furthermore, annual executive meetings are held to review and summarize all QM issues each year.

2. RESOURCES

21.10 Explanatory note: The granting of ISA/IPEA status means that the Authority has demonstrated it has the infrastructure and resources to support the search and examination process. Chapter 21 calls for assurance that the Authority can continually support this process while accommodating changes in workload and meeting QMS requirements. The responses below, should provide this assurance.

Human resources:

(i) Provide information about the infrastructure in place to ensure that a quantity of staff: sufficient to deal with the inflow of work;

which maintains the technical qualifications to search and examine in the required technical fields; and

which maintains the language facilities to understand at least those languages in which the minimum documentation referred to in Rule 34 is written or is translated

is maintained and adapted to changes in workload.

(ii) Describe the infrastructure in place to ensure that a quantity of appropriately trained/skilled administrative staff is maintained and adapted to changes in workload:

at a level to support the technically qualified staff and facilitate the search and examination process, and

for the documentation of records.

Substantive examiners

The search and substantive examination of international applications are performed by the Patents Department. This department includes 116 full-time substantive examiners (see the Table below) holding degrees in science, engineering, human and veterinary medicine from prestigious universities such as the Israel Institute of Technology - Technion, Weizmann Institute of Science and the Hebrew University of Jerusalem.

Technical field	Number (in full-time equivalent)	Average experience as examiners (years)	Breakdown of qualifications Ph.D. degree: [P] Master's degree: [M] Bachelor's degree: [B]
Mechanical	28	5	11% P, 72% M, 17% B
Electrical/electronic	34	6	12% P, 73% M, 15% B
Chemistry	37	10	38% P, 62% M
Biotech	17	10	41% P, 59% M
<i>Total</i>	<i>116</i>	<i>7.62</i>	<i>24% P, 67% M, 9% B</i>

About 30% of the examiners have more than 10 years' experience in their respective technical field, the majority of them hold Master's degrees and about 24% of them hold Ph.D. degrees. The minimum qualifications set for patent examiner candidates include a Bachelor's degree in

sciences, engineering or medicine and high writing skills in Hebrew and English. A third language will add credit in favor of the candidate. The ILPO examiners have the language skills to comprehend at least those languages meeting the minimum documentation requirement under PCT Rule 34, as well as several others. Some examiners also have mother-language level of Arabic, Russian, French, Ukrainian, Amharic, Romanian, Spanish, Italian, German and Portuguese. All of examiners possess bilingual, and some of them trilingual or quadrilingual capabilities.

Israel is known for its advanced technology and large number of high-tech companies in many diverse fields. The ILPO patent examiners are all experts in their fields. Previous to employment by the ILPO, many of the patent examiners were employed in their industrial field and are therefore well versed in the related technology. This diversity in examiner competencies is warranted by the multi-faceted structure of our national industry.

Trainee patent examiners undergo a two-year training program providing the examiners with a broad understanding of patent prosecution and its legal aspects, and develops their proficiency in performing prior art searches and their competence in examining patent applications (for more details please see "Training resources" below).

Examiners are further encouraged to participate in seminars and courses in their respective technical fields in order to maintain their competencies at a high level and up-to-date.

Each substantive examiner takes charge of performing classification of subject matter for the national and PCT applications, search, recording the search queries in a search strategy report, drafting an examination report (Office Action for national applications; written opinion for PCT applications) in which the objections under the relevant national or PCT statute are raised.

In the substantive examination of PCT applications, the following staff are involved:

- Substantive examiner, taking charge of the search, substantive examination and establishing the international reports as mentioned above;
- Optionally, an expert examiner, who works together with the substantive examiner, especially in cases involving multidisciplinary fields; and
- Quality control reviewer (team managers) for checking the international reports of the ISA/IL (ISRs, written opinions, invitations to pay additional fees) as well as the IPEA/IL (IPRP-Chapter II, invitations to pay additional fees) before being sent to the applicant.

[In 2018, ten new patent examiners have been recruited to the ILPO and have started their 2-year training program which has been recently upgraded.](#)

In 2016, 15 new substantive examiners have been recruited to the Patents Department and have started a newly structured two-year training program (please see "Training resources" below).

Team managers

The team managers take charge of the quality checking of the substantive examination, workload management, providing professional support to the examiners in search and examination as well as other managerial tasks.

In 2018, two new team managers, in the fields of physics and mechanics & electronics, have been appointed, thus reaching a total number of 13 team managers in 7 different technical fields.

In 2015, four new Managers have been appointed for the chemistry and pharmaceuticals teams.

Formalities examiners

The administrative tasks of the ILPO in its capacity as an International Searching and Examining Authority are performed by the staff of the PCT Department who have gained much experience in PCT-related proceedings. These tasks include processing all International Applications for which the ILPO serves as the ISA, processing Demands for International Preliminary Examination, mailing of notices and reports, monitoring timeliness and pendency of PCT search and examination reports by maintaining systems for tracking application status and workflow, as well as other administrative duties.

The PCT Department has highly skilled and qualified administrative personnel comprising the Department Director, two clerks and 8 PCT formalities examiners responsible for PCT work in the Receiving Office, the ISA/IPEA and the designated/elected Office. All of the formalities examiners have at least a Bachelor's degree and the majority of them hold a Master's degree in sciences and engineering.

Information & Database Manager

An Information & Database Manager was appointed in 2013 to take charge of the support (compliance with PCT Rule 34; implementation of updates, new features and training courses provided by the database service suppliers; maintenance and troubleshooting) of the search databases available at the ILPO (please see "Material resources" below) and of training programs organized or coordinated by the ILPO for the substantive examiners.

Material resources:

(iii) Describe the infrastructure in place to ensure that appropriate equipment and facilities such as IT hardware and software to support the search and examination process are provided and maintained;

(iv) Describe the infrastructure in place to ensure that at least the minimum documentation referred to in Rule 34 is available, accessible, properly arranged and maintained for search and examination purposes. State whether it is on paper, in microform or stored on electronic media, and where.

(v) Describe how instructions:

to help staff understand and adhere to the quality criteria and standards; and;

to follow work procedures accurately and consistently

are documented, provided to staff, kept up-to-date and adapted where necessary.

(iii-iv) Material resources infrastructure

- Automated systems for processing patent applications

In 2012, the ILPO has created a paperless work environment for the formalities and substantive examination of national and international patent applications.

- Automated system for national applications

The automated system for national applications supports electronic storing of patent files, Office Actions and communications from the applicants/agents. The applications are published on the internet website of the ILPO, after 18 months from the priority date, including all the application files (description, claims, drawings, sequences) and incoming/outgoing correspondence throughout all the processing stages. The national patent data is shared with other Offices in XML format.

An upgraded internal automated system for the processing of national applications has recently been developed, improving the work environment (including, *inter alia*, standardized clauses) and extending the documentation scope of structured data (including, *inter alia*, citations and CPC codes). ~~The system is currently in pilot stage~~ The new internal system is fully operative and currently used by ILPO staff.

- Automated system for PCT applications

Concerning international applications, the ILPO has developed a modern and efficient PCT automation system, entitled PCT-SAPIA (**S**ystem for **A**dministration and **P**rocessing of **I**nternational **A**pplications) to create a paperless work environment in processing the international applications at the RO, ISA and IPEA stages. The processes managed through this system include: electronic filing of international applications, receiving and storing all relevant documents from the applicants, handling and processing them according to the relevant PCT regulations (receipt, marking and formalities examination) and sending them to their destination, all under strict security. The incoming and outgoing correspondence with the applicants is documented in the system. The system fully supports upload and download of electronic documents and data between the local PCT RO/ISA/IPEA and the International Bureau.

This system implements a full scale of automated validations (including fees) and a full set of automated, online, secure communications with the applicants and the International Bureau of WIPO through EDI.

Furthermore, PCT-SAPIA includes all the checkboxes and text fields of the most current PCT forms which are used at the RO/ISA/IPEA stages under Chapter I and Chapter II of the PCT (for example PCT forms 103, 106, 110, 203, 206, 210, 237, 405, 408, 409, 428, 429). The system enables and supports advanced text formatting (especially in the field of "Citations and explanations" in the Ch. I/II written opinion / IPRP). After filling the relevant checkboxes and text fields in the system, PDF files of the PCT forms are automatically generated. The PCT forms can also be created in XML format.

Since January 2015, every invitation sent to the applicant to pay additional fees (PCT form 206) is accompanied by a partial search report concerning those parts of the international application which relate to the first invention.

The system includes a task list for the substantive, formalities and quality control examiners, and payment coordinator with built-in reminders to alert them about deadlines.

An automated information system applying Business Intelligence (BI) technology has been implemented for tracking and monitoring the timeliness of the different stages of international application processing, namely:

- sending priority documents to the IB;
- sending record copies to the IB;
- processing and sending search copies to the ISAs; and
- processing and sending international search reports and written opinions.

The management of the ILPO has access to statistical tools for calculating the workload of each examiner and department, and monitoring fluctuations in demand and backlog in a very transparent way.

o Automated allocation mechanism

An automated allocation mechanism in the internal systems has been developed to improve the way applications are allocated to examiners.

o E-filing systems

As part of the ILPO's commitment to improve its services and maintain high-level user satisfaction, a PCT e-filing system has been launched since July 2012 enabling applicants to file the international applications in electronic form and pay the relevant fees online.

In July 2016 ILPO's PCT Department launched a new electronic filing website and services. The new electronic website, which requires a "smart card", allows applicants to access application files maintained by the RO/ISA/IPEA/IL and to file post-filing documents in electronic form.

As of July 20, 2016, the ILPO in its capacity as receiving Office (RO/IL) started to receive and process PCT applications filed using ePCT-Filing (in addition to PCT-SAFE software) in accordance with the Israel Patent Law and Regulations. Applicants filing international applications with the RO/IL are able to use ePCT to generate a ".zip" file containing a validated request form, and then submit the ".zip" file electronically as part of an international application filed using the ILPO's electronic filing website.

This upgrade in the PCT e-filing system has been preceded by launching an e-filing system for national applications in December 2015, which has allowed applicants to receive Office Actions and other documents from the Patents Department by email (instead of regular mail). As of June 20, 2016, corporations or licensed representatives of applicants have been restricted to file new national applications and other documents to the ILPO only through the new e-filing system using an electronic certificate (smart card), while unrepresented private applicants may file the national application either via the new e-filing system or on paper.

o Reporting tool for ISA/IL applications filed at RO/US

For the handling of PCT applications filed at RO/US, a new management reporting tool has been developed in 2016 and made available on the ILPO website. This tool enables instantaneous access to ISA/IL databases, allows keeping track of the 100 applications limit per quarter and permits collaboration and coordination amongst geographically dispersed receiving Offices (RO/US and RO/IB).

- Transmission of extended national phase data to WIPO for PCT applications
Following the amendments to PCT Rules 86 and 95, which came into force from July 1, 2017, the ILPO has ~~started~~been providing WIPO, on a monthly basis since 2017, broadened information concerning national phase entry in XML format.
- Payment netting pilot
In order to reduce exposure of WIPO's fee income to movements in currency exchange rates and to improve the management of the transfer of PCT fees to the IB the ILPO, in its capacity as an RO, joined the netting pilot.

- Search databases available at the ILPO

Five advanced commercial search databases have been made available for all the substantive examiners, in addition to the national collection that can be searched by the internal automated system for national applications (and also on the ILPO's internet website):

- Derwent Innovation providing access to core patent collections, Derwent World Patents Index (DWPI), Derwent Patent Citations Index (DPCI), Asian translated patent collections and scientific literature collections;
- STN (REGISTRY, CAPIus, MARPAT, BIOSIS, CABA, MEDLINE, EMBASE, FSTA, USGENE, DWPI, DCR, DGENE, INSPEC, COMPENDEX, ENCOMPLIT, TULSA, INPADOC, Patent Full Text, REAXYSFILE) providing access to patent and non-patent literature, chemical structure database, biological sequences database and full-text machine translations;
- Orbit (Questel)~~(FamPat)~~ providing access to core patent collections as well as full-text machine translations; and
- PatBase providing access to core patent collections as well as full-text machine translations.

These search databases provide coverage far beyond the minimum documentation requirement of the PCT. In addition, the ILPO has purchased licensed access to full-text non-patent literature.

- Information exchange and cooperation with other Offices

- WIPO CASE
In 2014, the ILPO has joined the WIPO CASE system as an accessing office as well as a depositing office.
- PPH arrangements
In order to promote international work sharing, the ILPO has signed PPH & PCT PPH arrangements with a number of Patent Offices. In addition, as from January 6, 2014 the ILPO is part of the Global PPH arrangement. These arrangements have contributed to improving the efficiency, cost-effectiveness and quality of patent examination.
- Implementation of CPC system
An agreement was signed with the USPTO concerning the classification of IL national applications according to the CPC. According to the agreement, the ILPO classifies patent applications, which have been first filed in Israel since September 2016,

according to the CPC (in addition to the IPC), and the USPTO classifies the IL applications having corresponding applications that are already classified according to the CPC.

- WIPO Academy Internship Program

A 5-day annual course in patent search and examination in certain fields, organized by WIPO in cooperation with the ILPO, is provided to participants from WIPO Academy and other Offices at the ILPO since 2012. The course includes lectures about the legal and practical aspects related to the examination of patent applications at the ILPO, workshops and visits to industrial firms and academic institutions. The course also opens the opportunity for discussions and professional information exchange between the participants and ILPO examiners.

In October 2018, the course was directed to the fields of the pharmaceuticals, chemistry and biology and attended by 7 participants from other Offices. The course topics included issues of obviousness regarding pharmacokinetics, combinations, different populations, polymers, synergism and diagnostic & prognostic biomarkers; issues of biological mechanisms; maintaining crop diversity and the Treaty for Genetic Resources in Food and Agricultural Plants; CRISPR- CRISPR/Cas system and associated systems from the patents perspective; bioisosterism; eligibility of claims relating to plant and animal varieties and microorganisms; ethics and morality issues regarding patents in biotechnology; comparative law regarding eligible subject matter; and support of the claims by the description.

In March 2017, the course was directed to the field of Information and Communication Technology (ICT) and attended by 15 participants. The course topics included internet of things, deep learning, machine translations, social networks and big data.

In April 2016, the course was conducted in the pharmaceutical field and attended by 8 participants from WIPO Academy and 8 participants from other Offices (Finland, Spain, Poland and China).

- Technology and Environment employed by the ILPO

- Workstations

The ILPO patent examiners are equipped with workstations having access to the internal automated systems for examining national applications and international applications (PCT-SAPIA), and to high-speed internet. Each workstation is provided with a CD-ROM drive and two computer monitors. This provides patent examiners with the necessary facilities to conduct their search and examination functions.

- Teleworking

Examiners, whose residence is outside Jerusalem, have been provided with teleworking facilities, since 2010, to enable up to 50% home working. The ILPO was the first unit in the Ministry of Justice to implement the teleworking project which currently includes about 3940% of the substantive patent examiners. The teleworking project has been extended to include also PCT formalities examiners, in addition to the existing substantive examiners.

- Intranet
The ILPO's intranet provides access to the national and PCT legal texts; Commissioner's Circulars and Notices; Examination Guidelines; links to databases and information sources covering legal, patent and non-patent information; internal instructions; Quality Manual; team meetings (dates of the meetings and summary of the discussions and conclusions); training material; and advanced editing tools (OCR, splitting/merging documents, inserting pages, converting files to PDF, converting PDF files to MS Office documents).
- Information technology infrastructure
The ILPO's Service Management implements the Information Technology Infrastructure Library (ITIL) Standard the most widely accepted approach to IT service management in the world. The ILPO adopted a disaster recovery policy and has implemented GeoCluster which protects the organization from equipment failures, power outages and natural disasters. The ILPO's Server farm operates on a very high data security level, using several firewalls and strict security policy.

(v) Documentation of instructions

The Patent and PCT Departments have created their own internal (intranet) sites for the benefit of these units. Each internal site includes up-to-date Work Manuals (including, *inter alia*, the guidelines for the examination of national applications), PCT legal texts (including, *inter alia*, the guidelines, instructions and standards) and communications (including, *inter alia*, circulars from WIPO), notifications, presentations, announcements, etc., thus improving the efficiency of the work process.

As part of the ILPO efforts to reduce the regulatory burden, the Commissioner Circulars have been updated and summarized to only two Circulars, issued in March 2017, relating to the substantive and formalities examination of patent applications.

Training resources:

(vi) Describe the training and development infrastructure and program which ensures that all staff involved in the search and examination process:

acquire and maintain the necessary experience and skills; and

are fully aware of the importance of complying with the quality criteria and standards.

Training resources for substantive examiners

- Trainee substantive patent examiners

A comprehensive training program for trainee patent examiners is in place. The ILPO training system has been developed so as to allow rapid recruitment and training of as many new examiners as required.

Trainee patent examiners are trained and supervised by senior examiners for a period of 24 months. Senior examiners, acting as personal mentors for the trainees, take charge of reviewing and approving the work and reports prepared by the trainees throughout the training period. During this period, the trainees participate in in-house training programs

comprising a basic course that imparts an in-depth insight into the various legal and practical aspects in the processing of patent applications. A 10-week incubator training program has been developed and implemented for the trainee patent examiners recruited in 2016. The training program includes theoretical and practical topics in search and examination practice at the ILPO. During this program, the trainees are trained to perform search and examination on pre-selected samples and to draft national and international reports. Evaluation forms, for assessing the progress of the trainees in each subject of the incubator training program, have been established and filled on a weekly-basis by the personal mentors. In addition, feedback from the trainees about the training program has been also collected. These training programs also confer upon trainees a broader perspective of the patent system, such as the role of patents as an economical tool for enhancing innovation and as a strategic business tool for companies.

The trainees are authorized to make their own decisions after thorough verification of their competencies and skills. At the end of each year during the training period, the examiners undergo a theoretical exam (legal aspects and practice) as well as a practical exam (examining a patent application). Upon successful completion of a final exams they are awarded a patent examiner certificate, approved and signed by the Commissioner, and are authorized to work independently and sign Office Actions and international reports without direct supervision.

- All substantive patent examiners

- Regular training programs

All patent examiners are kept up-to-date as to relevant changes in patent related legislation, practice and procedures. There are also regular training activities on improved search tools.

Examiners are encouraged to participate in seminars, workshops and courses in their respective technical fields, covering practices in searching, examination and using search databases, in order to maintain their competencies at a high level and up-to-date. In addition to the frontal training courses in search databases (Derwent Innovation, STN, EPOQUE Net, Questel and PatBase), examiners are encouraged to enroll in distance learning courses of the European Patent Academy and a follow-up is made of the training events of the Academy.

An examiner who has been authorized to work independently carries out searches and examinations of applications without strict supervision. However, decisions on refusal of acceptance or direct acceptance (without any Office Action) must always be discussed with and approved by the team manager.

In the periodic team meetings of the Patents Department, the substantive examiners raise cases for discussion concerning the substantive examination of the national and international applications. Prenotifications and the summaries of these meetings are posted in the intranet site of the Patents Department and made available to all examiners.

○ CPC training

In September 2017, a 5-day advanced training course in CPC was provided by the USPTO to ILPO examiners. The course included lectures and workshops in specific technical fields.

In July 2016, a 5-day training course in CPC was provided by the USPTO to the ILPO examiners at the ILPO. The course included general lectures on CPC as well as workshops in specific technical fields.

In May 2016, ILPO examiners enrolled in CPC-related distance learning courses provided by the EPO Academy.

In order to assure the appropriate implementation of the CPC system, a team has been appointed for providing support as well as verifying the correctness of the classification codes selected by the substantive examiner for each application first filed in Israel. Moreover, a CPC quality checklist has been established for use by the CPC team.

○ Professional courses

The training program for patent examiners has been improved to include mapping of training needs, depending on, inter alia, the technical fields showing high numbers of filings, high numbers of Commissioner or Court decisions, and new scientific and technological advances. Accordingly, several advanced professional courses have been held at the ILPO, provided by leading Israeli universities and private firms. The courses have covered the fields of data telecommunications, pharmaceuticals, electro-optics and electronics and focused on the last developments in these fields.

In 2017, a course in electro-optics and electronics was provided to ILPO examiners by a private firm specialized in offering training and consulting services.

In 2016, a course in "Principles of Pharmacy Sciences" has been held at the ILPO for patent examiners on a weekly basis, 4 hours a week. The course is provided by the Hebrew University of Jerusalem and covers in-depth knowledge about drug development, medicinal chemistry, general and clinical pharmacology, drug metabolism, drug delivery systems, immunotherapy, treatment of cardiovascular and CNS diseases, and pain management.

An annual training program concerning the patent legal aspects has been launched at the ILPO since 2015. This program includes lectures on administrative law, case law, amendments in the Israeli Patents Law and Regulations, legal implications and implementations of certain Sections of the Patents Law, comparative law, and training in legal search databases.

A course in reading engineering drawings is being conducted at the ILPO since December 2015. This course is intended to enhance the efficiency of the search and substantive examination by improving the competency of patent examiners in reading, understanding and interpreting engineering drawings.

A professional course in the field of data telecommunications was held in 2014 (15 weeks, 4 hours/week) at the ILPO by lecturers from a private firm specialized in industrial consulting and training.

- Training the trainers

In April-May 2016, part of the senior patent examiners participated in a 25-hour mentoring course that included theoretical and practical aspects in teaching and giving feedback. This course is intended to provide the senior examiners with modern training methodologies and enhance their training proficiency so that they are qualified to act as personal mentors for the trainee patent examiners, accompanying them during their 2-year training period till they become independent examiners. [A second advanced mentoring course has been provided to senior examiners in 2018.](#)

Training resources for the Administrative staff – PCT formalities examiners

Formalities examiners receive appropriate training relating to the entire PCT system.

Every new PCT formalities examiner undergoes two years of training, beginning with a general course, tutoring and periodic exams. During this training period, trainees participate in in-house training programs that impart in-depth insight into the PCT processing procedure.

The training programs include understanding and practicing the PCT legal texts including the Patent Cooperation Treaty, PCT Regulations, the contents of PCT International Search and Preliminary Examination Guidelines, Receiving Office Guidelines, as well as Administrative Instructions under the PCT.

PCT formality examiners are authorized to make their own decisions after thorough verification of their competencies and skills. At the end of each year, during the training period, the examiners take an exam. Upon successful completion of a final exam at the end of the training period they are awarded a PCT formalities examiner certificate, approved and signed by the Commissioner. Only after this period they may work independently and sign formal paper work without direct supervision.

The executive formalities examiner, acting as a personal tutor for a new examiner, takes charge of reviewing and approving the work and reports prepared by the new examiner throughout the training period.

All employees (new and senior) are regularly kept up-to-date by the Director of the PCT Department regarding all new PCT Circulars and any change in the Regulations and Guidelines. The procedural issues relevant to these updates are then discussed. Following such discussions, the employee in charge of Quality Assurance publishes revised "Internal procedure instructions" on the Intranet site and all staff members are committed to following these instructions, thus assuring uniformity.

The PCT Department holds periodic team meetings for the formalities examiners discussing all the issues raised concerning the processing of international applications at all their stages (RO, ISA/IPEA and national phase). These meetings are posted on the intranet site of the PCT Department.

The PCT Department's staff also took an active part in the ISEP – training the unit's examiners to fulfill their administrative duties as if a real search had been carried out and issuing forms accordingly. The results were thoroughly analyzed, and measures were taken to eliminate any structured discrepancies identified in the Pilot. All these reports were also subjected to a quality review by a team of senior examiners.

Research projects for candidates to senior examiners

Since 2014, part of the tasks assigned for patent examiners have involved research projects in various subjects related to the processing of applications. These projects include collecting, processing and analyzing comparative data, drawing conclusions, and providing suggestions for improvement or change in legislation, practice or policy. The projects are assessed by the ILPO management and are considered a pre-requirement for promotion to senior examiners.

Study visits to the industry and academic institutions

The ILPO regularly organizes visits for the examiners to industrial firms and academic institutions in Israel. In these visits, tours and lectures are provided to the examiners and discussions are held with the representatives concerning the scientific, technological, and IP-related aspects in various advanced technical fields.

[In November 2018, a study visit was made by 20 examiners to IBM Research – Haifa. The study included lectures and explanations about the company's contribution to innovation and its current and future computing and communication technologies; and discussions about IP-related aspects.](#)

[In December 2017, a study visit was made by 14 ILPO examiners to Bio-Technology General Israel – BTG in Kiryat Malachi. The visit included a tour in the company's manufacturing facility as well as lectures and explanations about the products of the company, the economic model on which the company's activity is based and IP-related aspects.](#)

In June 2017, a study visit was made by 18 ILPO examiners to Medtronic – Given Imaging Ltd. in Yokne'am. The visit included lectures and discussions about the development of capsule endoscopy and other products in the presence of one of the founders of Given Imaging; a discussion with an IP representative and a factory tour.

In March 2017, a study visit was made by 18 ILPO examiners to Merck in Israel, Yavne. The visit included lectures and discussions about the research activities in medical, biotechnological and pharmaceutical fields as well as in LCD technology; a discussion with an IP representative; and a tour in the research labs.

In November 2016, a study visit was made by 12 ILPO examiners to Compugen, a genomics-based drug and diagnostic discovery company, in Holon. During the visit, the examiners learned about the methods used by Compugen in discovering the developing new drugs.

In June 2016, another study visit was made by 17 ILPO examiners to Applied Materials Israel Ltd in Rehovot. The examiners learned about company's semiconductor technology.

In June 2016, a study visit was made by 8 ILPO examiners to Hadasit, the Technology Transfer Company of Hadassah Medical Organization (HMO) in Jerusalem.

In May 2016, a study visit was made by 17 ILPO examiners to HP Indigo plant in Kiryat-Gat. The different printing technologies were explained to the examiners including that of HP Indigo. The visit included a factory tour to learn about the products (inks, printing systems) of the company.

In 2015 a study visit was made to the USPTO in order to learn about the legislation, practice and experience relating to patent eligible subject matter. This visit is part of the preparations

done at the ILPO for examining international patent applications in the field of business methods.

A visit to Tel-Aviv University was organized by Ramot at Tel Aviv University Ltd. (Tel-Aviv University's technology transfer company) for patent examiners in 2014. In this visit, the latest researches and advanced scientific equipment in the field of nanotechnology were presented to the examiners in this field.

Offshore training

[In June 2018, two ILPO examiners participated in a 3-day CPC field-specific training in The Hague organized by the EPO.](#)

In May 2017, two senior examiners joined an advanced CPC training course in The Hague organized by the EPO.

In November 2016, 2 ILPO examiners took part in the examiner exchange program at the JPO concerning data processing and data interface. The practice of each Office in search and examination in these fields was shared.

In June 2016, a 2-day general and advanced CPC training course, organized by EPO, was held in The Hague and was attended by 3 ILPO examiners.

In order to proceed with the tasks involved in becoming an ISA/IPEA our examiners made a study visit to ROSPATENT and the USPTO in 2011 in order to learn from their experiences regarding handling international applications.

Other training resources

Trainings and seminars are held on a regular basis for the examiners from the Patent and PCT Departments. They are initiated by either the quality manager, as a result of quality checks, or by management in response to new instructions or new features in the automated system.

There is ongoing training for all staff involved in search and examination including training sessions and workshops on search databases; in-house seminars on IP, search and examination; discussion forums with agents and professional organizations of IP stakeholders, including industry; and management training.

A training in processing international applications related to methods of doing business and software was conducted by a representative of the USPTO in 2014.

Oversight over resources:

(vii) Describe the system in place for continuously monitoring and identifying the resources required:

to deal with demand; and

comply with the quality standards for search and examination.

Department Directors together with the Director of the ILPO are responsible for continuously monitoring and identifying resources required to deal with demand and comply with the quality standards for search and examination. Please see also Section 3 below.

3. MANAGEMENT OF ADMINISTRATIVE WORKLOAD

21.11 Indicate how the following practices and procedures for handling search and examination requests and performing related functions such as data-entry and classification are implemented:

- (i) Effective control mechanisms regarding timely issue of search and examination reports to a quality standard as set by the respective Authority; and*
- (ii) Appropriate control mechanisms regarding fluctuations in demand and backlog management.*

(i) Control mechanisms regarding timely issuing of search and examination reports

As mentioned under paragraph 21.10(i-ii) above, the administrative tasks of the International Searching and Examining Authority include processing all International Applications for which the ILPO serves as the ISA, processing Demands for International Preliminary Examination in its capacity as an IPEA, mailing of notices and reports, monitoring timeliness and pendency of PCT search and examination reports by maintaining systems for tracking application status and workflow, as well as other administrative duties. These duties are performed by the staff of the PCT Department who have a wealth of previous experience in a wide variety of PCT-related matters.

With respect to handling all the tasks involved in processing international applications at the RO and ISA/IPEA stages, the automated system (PCT-SAPIA) provides a quality assurance mechanism ensuring the timely issuance of international reports and communications (please see also Section 4 below).

(ii) Control mechanisms regarding fluctuations in demand and backlog management

The Patents Department and the PCT Department use Business Intelligence (BI) system for monitoring the workflow and providing indications to the timeliness of processing international applications and backlogs.

Management continuously monitors both fluctuations in demand and possible backlogs to ensure there are enough resources available at all times.

Information mentioned in (i) and (ii) can be extracted from the ILPO's IT systems, and reports concerning this information are generated for management.

4. QUALITY ASSURANCE

21.12 In accordance with the Guidelines, the following are required quality assurance measures for timely issue of search and examination reports of a high quality. Indicate how the following are implemented, including the use of any checklists to verify reports before their issue or for monitoring the quality as part of a post-issue review process:

(i) An internal quality assurance system for self-assessment, involving verification, validation and monitoring of searches and examination work:

for compliance with these Search and Examination Guidelines;

for channeling feedback to staff.

(ii) A system of measurement and collection of data and reporting. Show how the Authority uses the system to ensure the continuous improvement of the established processes.

(iii) A system for verifying the effectiveness of actions taken to correct deficient S&E work, eliminate the causes, and to prevent issues from recurring.

The Quality Manager reports directly to the Director of the ILPO in matters regarding quality of services and the QMS from the data available to him and from the feedback from the directors of departments, managers of teams, examiners and customers.

A mechanism has been established for the periodic update and follow-up of the Examination Guidelines to meet certain needs such as improved examination standards, improved user services or changes in legislation and practice. This mechanism involves Management, Quality Manager, Examination Guidelines Team and Improvement Team (for more details please see "Continual improvement progress" under Section 1 above).

The manager of each technical team (computers and communications, mechanics, physics, medical devices, biotechnology, pharmaceuticals and chemistry) in the Patents Department is responsible for the quality checking of the national Office Actions and the international reports produced.

Directors of the Patents Department are responsible for the control of resources, guiding of work and the uniformity of practices among the different technical teams. The objective is to ensure that the same approach and practice is adopted in the search and examination of all patent applications, irrespective of which team performed the task.

To help examiners prepare written opinions and IPRPs more efficiently, written opinion samples from other Offices have been collected and the most frequently used clauses in the written opinions have been made available to the examiners. Since April 2015, Standardized Clauses, prepared by the Standardized Paragraphs Pilot Working Group, has been made available to the examiners to be implemented in the ISA and IPEA reports.

The PCT Department has a quality coordinator who is in charge of quality related matters and also responsible for the control of resources, guiding of work and the uniformity of practices among the formalities examiners. The objective is to ensure that processing of an international application leads to the same result irrespective of which examiner performed the task.

The staff of the PCT Department meets regularly in order to deal with any business-related problems, and in order to keep examiners informed of important changes in the PCT system. Concerning the quality of formalities examination of international applications, in addition to the use of checklists and follow-up of timeliness, the PCT Department in its capacity as RO/IL

conducts on a monthly basis careful analysis of invitations received from the IB for remedial work by the RO. The received PCT IB Forms (313, 321 or 345) are analyzed carefully by the Head of the PCT Department and QA Coordinator.

The collected information and results of analysis are evaluated carefully and taken into consideration for possible future amendments of the ILPO PCT internal guidelines, training, quality policy, etc.

The ILPO has established an internal quality assurance system for international reports, involving the evaluation of the administrative as well as the search and examination work to verify compliance with the PCT administrative instructions, the PCT Receiving Office (RO) Guidelines, PCT Search and Examination Guidelines and the internal instructions. This quality assurance system implements 3 types of checking procedures:

- Automatic quality checking by the automation system

As mentioned in Section 2 above (Material resources), the ILPO has developed a modern and efficient automation system entitled PCT-SAPIA (System for Administration and Processing of International Applications) to handle the processing of international applications electronically and to provide automatic quality checking of the formalities examination at the RO stage as well as the formalities and substantive examination at the ISA and IPEA stages. This system implements a full scale of automated validations (including warnings for nonconforming cases) and guidance (according to a predetermined work order) for the relevant examiner, thus preventing him/her from making mistakes and ensuring integrity of the reports. The system sends alerts to the relevant examiner as well as to the department directors in cases where the due dates are not met. This system provides electronic sampling of 100% of the applications. By this way, the amount of formalities and substantive errors in the international reports is minimized and the time needed in preparing the reports is reduced.

The family members of the cited patent publications are automatically retrieved by the system. Cited documents (especially non-patent publications) are uploaded into the system and linked to the relevant document cited in the ISR, enabling convenient and immediate retrieval whenever requested by the applicant.

In order to ensure the timely processing of international applications, a control mechanism has been implemented in the PCT-SAPIA. The PCT-SAPIA provides a task list for formalities, substantive and quality control examiners and for the payment coordinator, with built-in reminders to alert them and the administration of approaching deadlines. Each task is color coded to enable users to quickly determine when a time limit will expire. A daily query is run to determine the necessary action regarding the applications at hand. These applications are brought to the attention of senior staff members who take the appropriate action.

Active Task List (656)									
			Recommended for Closure	Stage	File No.	Task Type	User	Capacity	Due Date
>	▶	▶	▶	ISA	PCT/US2016/050121	Perform ISA Substantive Examination	El...	ISA Substantive Examiner	30 Sep 2016
>	▶	▶	▶	ISA	PCT/IB2016/001207	Perform ISA Substantive Examination	Ya...	ISA Substantive Examiner	18 Oct 2016
>	▶	▶	▶	ISA	PCT/US2016/060751	Perform ISA Substantive Examination	Td...	ISA Substantive Examiner	02 Oct 2016
>	▶	▶	▶	ISA	PCT/IL2016/050922	Perform ISA Substantive Examination	Lj...	ISA Substantive Examiner	25 Sep 2016
>	▶	▶	▶	IPEA	PCT/IL2015/050690	Perform IPEA Substantive Examination - Iteration in proce...	Il...	IPEA Substantive Examiner	20 Dec 2016
>	▶	▶	▶	ISA	PCT/IL2016/050932	Perform ISA Substantive Examination	Ev...	ISA Substantive Examiner	06 Nov 2016
>	▶	▶	▶	ISA	PCT/IL2016/051103	Create ISA/23 form	Sa...	ISA Formality Examiner	
>	▶	▶	▶	ISA	PCT/IL2016/050943	Create ISA/23 form	Ya...	ISA Formality Examiner	
>	▶	▶	▶	IPEA	PCT/IL2016/051175	Perform IPEA Substantive Examination - Iteration in process	Jo...	IPEA Substantive Examiner	22 Dec 2016
>	▶	▶	▶	RO	PCT/IL2013/999999	Unpaid file - Create late payment fee		Payment Coordinator	06 Dec 2013
>	▶	▶	▶	IPEA	PCT/IL2015/050414	Create New Iteration	Ol...	IPEA Substantive Examiner	19 Mar 2016
>	▶	▶	▶	IPEA	PCT/IL2015/0500773	Create New Iteration	Yo...	IPEA Substantive Examiner	23 Jun 2016
>	▶	▶	▶	IPEA	PCT/IL2015/0000037	Create New Iteration	Er...	IPEA Substantive Examiner	01 Jul 2016
>	▶	▶	▶	IPEA	PCT/IL2015/0000038	Create New Iteration	Er...	IPEA Substantive Examiner	01 Jul 2016
>	▶	▶	▶	IPEA	PCT/IL2015/050813	Create New Iteration	Ex...	IPEA Substantive Examiner	05 Jul 2016
>	▶	▶	▶	IPEA	PCT/IL2015/050921	Create New Iteration	Er...	IPEA Substantive Examiner	30 Jul 2016
>	▶	▶	▶	IPEA	PCT/IL2015/051044	Create New Iteration	Ol...	IPEA Substantive Examiner	29 Sep 2016
>	▶	▶	▶	IPEA	PCT/IL2015/051084	Create New Iteration	Yo...	IPEA Substantive Examiner	23 Sep 2016

The QMS includes also a number of built-in quality follow-up mechanisms in the PCT-SAPIA system to ensure a continuous improvement of the quality:

- Tasks for ISA QC Examiners. International reports (PCT forms 210, 237, 206, 405 and 409) prepared by substantive patent examiners are peer-reviewed by ISA QC examiners (highly skilled and experienced patent examiners) before being dispatched from the ILPO to the applicant and IB (please see also paragraph 3.2.1 below concerning substantive examination checking).
- Alerts for the examiners to upload in the system Search Strategies and search process checklists. The business rules implemented in the system are designed to help the examiners support the quality of the international reports produced. This is done by guiding the examiner automatically, and preventing him from missing the upload of search process checklists and search strategies when the search and examination has been completed. Thus, for example, before each report is completed it is checked by the system and if both the search process checklist and the search strategy are uploaded, without which the examiner receives an error message preventing further processing of the application.
- Self-checking by the examiner

The formalities and substantive examiners fill out checklists for each international application covering the steps to be completed at the RO and ISA stages.
- Checking by a quality control examiner and by a second examiner
 - At the RO stage, ~~40~~ at least 5% of the filed international applications are cross-checked by a second RO formalities examiner. The checking covers formalities issues such as bibliographical details, contents of the application and physical requirements under Rule 11. Since the beginning of 2018, 5.43% of the applications have been cross-checked.
 - At the ISA and IPEA stages, three kinds of checking are performed:
 - *Substantive examination checking:* The quality control reviewer checks 100% of the international reports (PCT forms 210, 237, 206, 405 and 409). In the cases where all the cited documents found by the substantive examiner are in [A] category, a second examiner performs a new search before issuing the ISR and the Written Opinion of the ISA. The quality control checking of the international reports has been integrated into the automated system for international applications (PCT-SAPIA). A task for QC

checking is sent to the relevant QC reviewer upon completion of the substantive examination, so that the international reports established by the substantive examiner, cannot be processed further without completing the QC checking. In addition to the quality checking of the reports, the search strategies are periodically checked.

- *ISA/IPEA formalities examination checking:* The ISA/IPEA formalities examiner performs formalities checks on all PCT forms (including search strategies) (100% sampling) to be sent to the applicant and IB, inspecting the integrity and consistency of the details in the forms.
- *Periodic audit of a random sample of cases:* ~~Approximately 9%~~At least 5% of the ISA/IPEA PCT forms of the international applications designating the ILPO as ISA/IPEA are cross-checked by a second ISA formalities examiner, using a quality assurance checklist. Audit findings and recommendations are recorded in the automation system. Since the beginning of 2018, 6.12% of the ISA forms and 48% of the IPEA forms have been cross-checked.

5. COMMUNICATION

Inter-Authority communication:

21.13 Explanatory note: Each Authority should provide for effective communication with other Authorities.

(Note: This point is informative. No response is required by the template to paragraph 21.13)

21.14 Provide the name, job title and contact details of the Authorities designated quality contact person who will take responsibility for:

- (a) helping identify and disseminate best practice among Authorities;*
- (b) fostering continual improvement; and*
- (c) providing for effective communication with other Authorities to allow for prompt feedback from them so that potential systemic issues can be evaluated and addressed.*

(a)-(c) Contact persons:

Mr. Moshe Cohen, Quality Manager: MosheCo@justice.gov.il

Dr. Imad Zakharia, Patent Examiner: ImadZ@justice.gov.il

Israel Patent office

Malcha Technology Park, Building 5

1 Agudat Sport Hapoel St.

Jerusalem 9695102

Israel

Facsimile No. 972-2-5651616

Communication and guidance to users:

21.15 Describe the system in place for monitoring and using customer feedback including at least the following elements:

- (i) An appropriate system for handling complaints and making corrections; taking corrective and/or preventative action where appropriate; and offering feedback to users.
- (ii) A procedure for: monitoring user satisfaction and perception; and for ensuring their legitimate needs and expectations are met.
- (iii) Clear, concise and comprehensive guidance and information to users (particularly unrepresented applicants) on the search and examination process, giving details of where it is to be found e.g. link to Authority's web site, guidance literature.

Indicate where and how the Authority makes its quality objectives publicly available for the users.

In order to improve the quality of PCT applications the ILPO has provided a number of mechanisms for obtaining feedback from applicants covering all processing stages of international applications:

- Communications between applicant/agent and examiner

In invitations, notifications and reports, the name of the examiner is given as well as their telephone number, fax number and email address.

Formalities examiners are encouraged to contact the applicant by email or phone in order to promptly clarify any ambiguities.

- User feedback

The ILPO uses a number of methods to collect user's feedback:

- Online External Quality Survey System:

The main method used to obtain feedback on the quality of the different services provided by the ILPO is the *Online External Quality Survey System* which has been conducted since 2011 on an annual basis by an external company. By this satisfaction survey, users have the opportunity to anonymously evaluate the services related to the receiving, processing, and formalities & substantive examination of applications. The evaluation is based on assigning a grade (from 1 to 5) for each service and providing comments and suggestions for improvement.

- Internal Quality Survey System

An internal electronic survey is conducted since 2011 on an annual basis for all ILPO departments and satisfaction feedback is collected from the ILPO staff together with suggestions for improvement.

- Commissioner's Consultative Forum (CCF)
Feedback is also collected through regular face-to-face meetings with Israeli IP professional associations including the Patent Attorney Association, the Israel Bar Association, AIPPI, FICPI, AIPLA and LESI (Israeli IP professional associations). These meetings typically focus on PCT processing, patents, trademarks & designs examination practice and procedures. The meetings are known as the Commissioner's Forum and are held periodically (once or twice per year).
- Roundtables
Roundtables are held by the PCT Department and the Patent Department with the users (patent agents, various industries, Universities, private applicants) in order to better understand their needs and to keeping them up-to-date on the latest developments in the national patent and PCT systems, and to increase awareness to new services offered by the ILPO. During these meetings compliments, suggestions and complaints are also collected.
- User Feedback on legal changes
New Commissioner Circulars and amended Examination Guidelines are posted on the ILPO website for a certain period in order to receive user feedback before they enter into force. This feedback is carefully taken into consideration by the ILPO in preparing the final versions of the Circulars and Guidelines.
- Other methods
Other means for receiving feedback include phone, fax, e-mail or personal meetings. Help Desks for the Patents Department and the PCT Department have been put in place to handle customer complaints, providing customers with assistance on a wide variety of patent-related matters.

Feedback is monitored by the ILPO's QA Manager who conducts analysis of feedback data, reports them to the top management and recommends the required measures for improvement. The results of customer feedback are evaluated and taken into consideration for possible future amendments of the ILPO internal guidelines, training, quality policy, etc.

- Guidance and information for users

Information, guidance and updates (in Hebrew, English and Arabic), including information concerning the filing and processing of national and international applications are provided on the ILPO website along with social media platforms such as Facebook. In addition, users can subscribe to the ILPO mailing list to obtain direct news feed. Regarding international applications, a link to the WIPO website, concerning PCT prosecution, is provided.

The guidelines for the examination of national applications are part of the QMS and are published on the ILPO's website.

The ILPO supports applicants facing difficulties in filing and e-filing national and international applications, and provides guidance and information for users by:

- Face-to-face communication (helping and advising how to file international applications);
- Telephone, fax and email;
- Holding seminars;
- Roundtables (upon request);

- Providing informative material on the ILPO Website.

A series of meetings, concerning the PCT process, e-filing, e-payment, overview of the RO, ISA, IPEA and national phase have been provided to agents. In these meetings, problems and potential improvements in PCT system have been discussed.

21.16 Communication with WIPO and designated and elected Offices:

Describe how the Authority provides for effective communication with the International Bureau and designated and elected offices. In particular describe how the Authority ensures that feedback is promptly evaluated and addressed.

Communication with WIPO and designated and elected offices is done through the PCT Department. This department addresses all feedback given by WIPO or designated and elected offices to the management of the office.

WIPO Circulars and high-level changes are directed to the Director of the PCT Department who ensures that all staff is aware of the issues and that any changes to the procedures are carried out.

The Director of the PCT Department and Deputy Superintendent of patent examiners regularly attend WIPO meetings.

Communication with the International Bureau of WIPO is mainly provided via PCT-EDI, by e-mail, facsimile and telephone.

The ILPO uses the EDI system for all communication with WIPO concerning international and national applications.

The ILPO has started providing WIPO, on a monthly basis, broadened information concerning national phase entry in XML format.

In its capacity as an International Searching Authority, the ILPO has started, since 2016, applying eSearchCopy system regularly for receiving international applications filed by US applicants at the US Receiving Office and by Israeli applicants at the RO/IB for which the ILPO is a competent International Searching Authority. Once received via PCT-EDI automated secure FTP protocol, the international applications are automatically uploaded to the internal automation system for further processing.

Starting from May 31, 2016 the RO/IL completely stopped the paper-based flow with the ISA/EP and as of that date all search copies and subsequently filed documents of the international applications, are transmitted to the ISA/EP only electronically via the IB.

In 2013, the ILPO PCT Department started using ePCT services for downloading "post-filing" documents in electronic form.

6. DOCUMENTATION

21.17 Explanatory note: The QMS of the Authority needs to be clearly described and implemented so that all processes in the Authority and the resulting products and services can be monitored, controlled, and checked for conformity. This is done by documenting the procedures and processes affecting the quality of work as a reference for staff and management at the Authority (see paragraph 21.18).

(Note: This point is informative. No response is required by the template to paragraph 21.17)

21.18 The material that makes up the reference for staff and management at the Authority serves to document the procedures and processes affecting the quality of work, such as classification, search, examination and related administrative work. In particular, the reference indicates where to find instructions on the procedures to be followed.

For the purposes of this report indicate:

- (a) the documents making up the reference that have been prepared and distributed;*
- (b) the media on which they are supported (e.g. Internal Publication, Internet, Intranet); and*
- (c) document control measures taken e.g. version numbering, access to latest version.*

The latest approved version of the Quality Manual and the Work Manual for each department of the ILPO (including the Patents Department and the PCT Department) are made available to the staff in the internal websites (intranets). Any update in the contents of the manuals is brought to the relevant department director for approval. Upon approval of any such update, the version number of the relevant document is updated and distributed to all staff in the relevant department, and published on the intranet site of that department. Documents belonging to previous versions are kept for follow up purposes.

21.19 Indicate whether the material making up the reference of quality procedures and processes include the following:

- (i) the quality policy of the Authority including a clear statement of commitment to the QMS from top management;*
- (ii) the scope of the QMS, including details of and justification for any exclusions;*
- (iii) the organizational structure of the Authority and the responsibilities of each of its departments;*
- (iv) the documented processes carried out in the Authority such as receipt of incoming applications, classification, distribution, search, examination, publication and support processes, and procedures established for the QMS, or references to them;*
- (v) the resources available for carrying out the processes and implementing the procedures; and*
- (vi) a description of the interaction between the processes and the procedures of the QMS.*

The Quality Manual includes items (i) to (vi) and all the instructions and procedures for the ongoing operation of the Quality Management System (QMS).

All ILPO employees are committed to work in accordance with the quality procedures. The ILPO utilizes control procedures in all departments for all of the activities therein, in order to verify that all requirements appearing in the Quality Manual and Work Manuals are being fulfilled.

Quality procedures and work instructions incorporate all activities of the ILPO among all its departments and are updated according to need.

21.20 Indicate which types of records the Authority maintains, such as:

- (i) a definition of which documents are kept and where they are kept;
- (ii) results of management review;
- (iii) training, skills and experience of personnel;
- (iv) evidence of conformity of processes, resulting products and services in terms of quality standards;
- (v) results of reviews of requirements relating to products;
- (vi) the search and examination processes carried out on each application;
- (vii) data allowing individual work to be tracked and traced;
- (viii) records of QMS audits;
- (ix) actions taken re. non-conforming products, e.g. examples of corrections;
- (x) actions taken re. corrective action;
- (xi) actions taken re. preventative action; and
- (xii) search process documentation as set out in Section 7.

In accordance with ISO 9001 standard the ILPO stores and maintains the Quality Manual, Work Manual and items (i) to (xii).

7. SEARCH PROCESS DOCUMENTATION

21.21 For internal purposes the Authority should document its search process.

The Authority should indicate

- (a) which of the following are included in this record:
 - (i) the databases consulted (patent and non patent literature);
 - (ii) the keywords, combinations of words and truncations used;
 - (iii) the language(s) in which the search was carried out;
 - (iv) the classes and class combinations searched, at least according to the IPC or equivalent;
 - (v) a listing of all search statements used in the databases consulted.
- (b) which other information relevant to the search itself is included in this record e.g. a statement of the subject of search; details of special relevance to internet searching; a record of documents viewed; on-line thesaurus, synonym or concept databases, etc.
(Explanatory note: The IA is requested to list other information it may collect to monitor and improve the search process)
- (c) which special cases are documented and whether records are kept denoting any:
 - (vi) limitation of search and its justification
 - (vii) lack of clarity of the claims; and
 - (viii) lack of unity.

The search process documentation for each application is stored in the PCT-SAPIA automated system. Since all the international reports of Chapter I and Chapter II (for example, PCT Forms 206, 210, 237, 408, 409, 428, 429) are prepared in the automated system, all the data in the reports is stored in the system. This data includes, *inter alia*, the databases consulted, the listing of search statements (search strategy), IPC classification of subject matter and minimum documentation searched, limitation of search and its justification, lack of clarity of the claims and lack of unity. The system supports documenting the notes raised by the examiner and the incoming/outgoing communications.

Since April 2013, the search strategy is stored in the system, transmitted to the applicant and the IB, and is published with the ISR.

8. INTERNAL REVIEW

21.22 Explanatory note: The Authority should report on its own internal review arrangements. These reviews determine the extent to which it has established a QMS based on the model of Chapter 21 and the extent to which it is complying with the QMS requirements and the Search and Examination Guidelines. The reviews should be objective and transparent to demonstrate whether or not those requirements and guidelines are being applied consistently and effectively and should be undertaken at least once a year. With reference to point 21.08 of this template, the Authority may provide additional information on its internal review arrangements under this section if it so wishes.

21.23-21.25 These arrangements are reported according to this template in Section 1, above, at points 21.04 - 21.09. The Authority may provide additional information on further inputs to its internal reviews under this section, if it so wishes.

Internal reviews take place at least once a year, in which the Quality Manager meets with an external quality consultant and receives feedback and support. These reviews are presented to top management at management reviews. Please see also Section 1 above (under paragraphs 21.08-21.09).

The Quality manager is responsible for controlling the extent to which the QMS complies with ISO 9001 requirements as well as to the chapter 21 of guidelines.

External reviews take place once a year and are held by an accredited quality auditor. Results are presented to top level management at management reviews.

9. ARRANGEMENTS FOR AUTHORITIES TO REPORT TO THE MIA

21.26 There are two stages in the reporting arrangements outlined in Chapter 21: the initial report called for by paragraph 21.26(a), and supplementary annual reports in accordance with paragraph 21.26(b). At the second informal meeting of the Quality Subgroup in Canberra on February 6 and 7, 2012, the Subgroup recommended that, instead of submitting full reports every five years and cumulative updates in the intervening years, Authorities should submit each report in the form of a full report, making the differences from the previous year's report clear, for example using "track changes" or other form of highlighting. The template for the supplementary annual reports is therefore no longer used.

Annex to the Report on Quality Management Systems by the ISRAEL PATENT OFFICE (ILPO), December ~~1402~~, ~~2017~~2018

Statistical Data

1. PCT international applications received by the RO/IL:

Year	2012	2013	2014	2015	2016	<u>2017</u>
PCT applications	967	1199	1211	1331	1429	<u>1417</u>

2. International Search Reports (ISRs) established by the ISA/IL (from RO/IL, RO/IB, RO/US):

Year	2012	2013	2014	2015	2016	<u>2017</u>
ISRs	163	746	867	1084	1352	<u>1416</u>

3. PCT applications published with ISR in 2016:

~~99.7%~~100% of PCT applications selecting the ILPO as ISA were published with the ISR in 2016 [see Patent Cooperation Treaty Yearly Review ~~2017~~2018, Figure C19:

~~http://www.wipo.int/edocs/pubdocs/en/wipo_pub_901_2017.pdf~~

~~http://www.wipo.int/edocs/pubdocs/en/wipo_pub_901_2018.pdf~~].

4. Average pendency to first examination of national applications: **29.5 months**.

5. User satisfaction survey results:

Year	2013	2014	2015	2016	<u>2017</u>
Average grade [%]	82.2	81.5	80.6	80.8	<u>80.6</u>