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## PATENT COOPERATION TREATY (PCT)

### Common Quality Framework for International Search and Preliminary Examination

#### INITIAL REPORT ON QUALITY MANAGEMENT SYSTEMS

*Prepared by the ISRAEL PATENT OFFICE*

*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)

*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*

[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 has a Quality Management System certified according to ISO 9001:2008. ~~At the moment, t~~he certification covers all services offered by the ILPO: processing of national

patent applications, ~~processing of~~ 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.

Over the course of the past four years, the ILPO has taken measures towards instituting a quality control framework for the processing of national applications. At present, quality control mechanisms at the ILPO already cover the requirements of the Quality Framework set out in Chapter 21 of the PCT International Search and Preliminary Examination Guidelines.

The ILPO has implemented the same quality control mechanisms for the processing of international applications.

As part of the ILPO's efforts to create a paperless work environment, the ILPO has established a computerized system for processing international applications at the RO and ISA/IPEA stages, and to enable the applicants to file the international applications electronically and pay the relevant fees online.

## 1. LEADERSHIP AND POLICY

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

- (a) The quality policy established by top management.
- (b) The roles and names of those bodies and individuals responsible for the QMS, as delegated by top management.
- (c) An organisational chart showing all those bodies and individuals responsible for the QMS.

### (a)

~~Quality is of paramount importance to the ILPO. Over the course of the past three years, we have taken measures towards instituting a quality control framework for the processing of national applications. At present, quality control mechanisms at the ILPO already cover the requirements of the Quality Framework set out in Chapter 21 of the PCT International Search and Preliminary Examination Guidelines.~~

~~The ILPO has implemented the same quality control mechanisms for the processing of international applications.~~

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 divisions of the ILPO. This manual is posted on the intranets of the ILPO divisions.

The ILPO's top management has delegated the role as Quality Manager as defined in ISO 9001:2008. This role is currently held by ~~Mr. Moshe Cohen,~~a senior patent examiner.

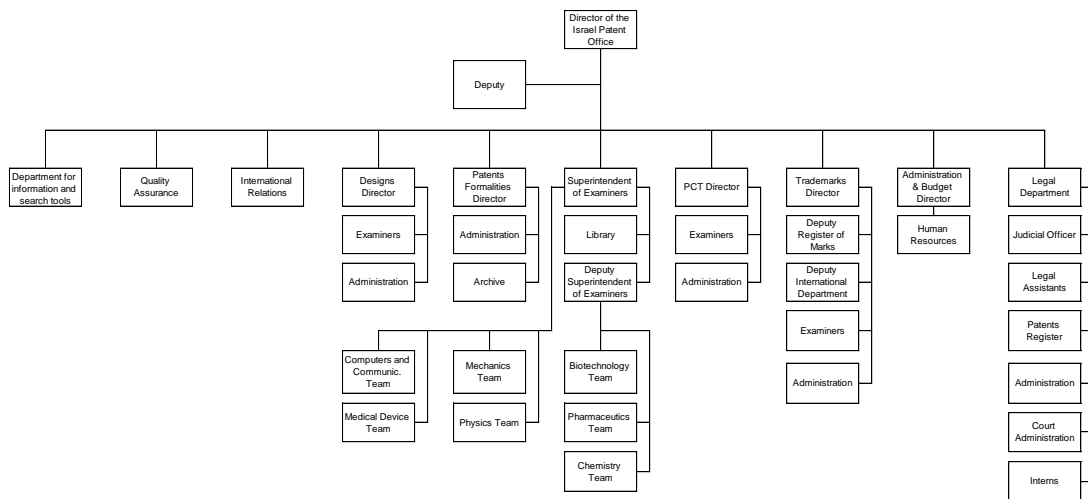
### (b)

The Quality Manager is responsible for the implementation and continuous improvement of the Quality Management System. The Quality Manager is in charge of the day to day implementation 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 9001:2008, 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;
- providing data for external audits.

(e) 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

Chapter 21 requirement			Extent of compliance		
			full	part	no
21.04	(a)	Quality policy available	v		
	(b)	Identified roles and names for QMS responsibility	v		
	(c)	Organizational chart available	v		
21.05		Established compatibility of QMS with Chapter 21	v		
21.06	(a)	Mechanisms to ensure effectiveness of the QMS	v		
	(b)	Control of the continual improvement process	v		
21.07	(a)	Communication of management about this standard to staff	v		
	(b)	The PCT Guidelines are in line with the Authority's QMS	v		
21.08	(a)	Management reviews take place	v		
	(b)	Quality objectives are reviewed	v		
	(c)	Communication of quality objectives throughout the Authority	v		
21.09	(a)	Performance of a yearly internal review of the QMS in/to	v		
	(b)	(i) determine the extent to which the QMS is based on Chapter 21	v		
		(ii) determine the extent to which S&E complies with PCT Guidelines	v		
	(c)	an objective and transparent way	v		
	(d)	using input incl. information according paragraph 21.17	v		
	(e)	recording the results	v		
21.10		Assurance to monitor and adapt to actual workload	v		
21.11	(a)	Infrastructure in place to ensure that a quantity of staff	v		
		(i) sufficient to deal with the inflow of work	v		
		(ii) which maintains tech. qualifications to S&E in all technical fields	v		
		(iii) which maintains the language facilities to understand languages according to Rule 34	v		
	(b)	Infrastructure to provide a quantity of skilled administrative staff	v		
		(i) at a level to support the technically qualified staff	v		
		(ii) for the documentation records	v		
21.12	(a)	(i) Ensuring appropriate equipment to carry out S&E	v		
		(ii) Ensuring documentation accord. to Rule 34	v		

Chapter 21 requirement			Extent of compliance		
			full	part	no
	(b)	(i) Instructions to help staff understand and act accord. the quality criteria and standards	v		
		(ii) Instructions to follow work procedures accurately and they are kept up-to-date.	v		
21.13		(i) L&D program to ensure and maintain necessary skills in S&E	v		
		(ii) L&D program to ensure awareness of staff to comply with the quality criteria and standards.	v		
21.14	(a)	System in place for monitoring resources required to deal with demand	v		
	(b)	System in place for monitoring resources required to comply with the quality standards in S&E	v		
21.15	(a)	Control mechanisms to ensure timely issue of S&E reports	v		
	(b)	Control mech. regarding fluctuations in demand and backlog	v		
21.16	(a)	Internal quality assurance system for self-assessment	v		
		(i) for compliance with S&E Guidelines	v		
		(ii) for channeling feedback to staff	v		
	(b)	A system for measurement of data and reporting for continuous improvement	v		
	(c)	System for verifying the effectiveness of actions taken to correct deficient S&E work	v		
21.17	(a)	Contact person helping identify best practice between Authorities	v		
	(b)	Contact person fostering continual improvement	v		
	(c)	Contact person providing for effective comm. with other Authorities for feedback and evaluation	v		
21.18	(a)	(i) Appropriate system for handling complaints	v		
		(ii) Appropriate system for taking preventive/corrective actions	v		
		(i) Appropriate system for offering feedback to users	v		
	(b)	(i) A procedure for monitoring user satisfaction & perception	v		
		(ii) A procedure for ensuring their legitimate needs and expectations are met	v		
	(c)	Clear and concise guidance on the S&E process for the user	v		
	(d)	Indication where and how the Authority makes its quality objectives publicly available	v		

Chapter 21 requirement			Extent of compliance		
			full	part	no
21.19		Established comm. with WIPO and desig. + elected offices	v		
21.20		QMS of Authority clearly described (e.g. Quality Manual)	v		
21.21	(a)	Documents making up the Quality Manual have been prepared and distributed	v		
	(b)	Media available to support the Quality Manual	v		
	(c)	Document control measures are taken	v		
21.22	(a)	Quality policy of the Authority and commitment to QMS	v		
	(b)	Scope of QMS	v		
	(c)	Organizational structure and responsibilities	v		
	(d)	the documented processes are carried out in the Authority	v		
	(e)	Resources available to carry out processes	v		
	(f)	a description of the interaction between the processes and the procedures of the QMS.	v		
21.23	(a)	Records which documents are kept and where they are kept	v		
	(b)	Records of results of management review	v		
	(c)	Records about training, skills and experience of staff	v		
	(d)	Evidence of conformity of processes	v		
	(e)	Results of reviews of requirements relating to products	v		
	(f)	Records of the S&E process carried out on each application	v		
	(g)	Record of data allowing individual work to be tracked	v		
	(h)	Record of QMS audits	v		
	(i)	Records on actions taken re. non-conforming products	v		
	(j)	Records on actions taken re. corrective actions	v		
	(k)	Records on actions taken re. preventive actions	v		
	(l)	Records referring to search process documentation		v	
21.24	(a)	(i) Recording of the databases consulted during search	v		
		(ii) Recording of keywords, combination of words and truncations during search	v	✗	
		(iii) Recording of the languages used during search		v	
		(iv) Recording of classes and combinations thereof consulted during search	v		
	(b)	Records about other information relevant to the search	v		
	(c)	(i) Records about limitation of search and its justification		v	

Chapter 21 requirement			Extent of compliance		
			full	part	no
		(ii) Records about lack of clarity of the claims	v		
		(iii) Records about lack of unity	v		
21.25		Report on its own internal review processes	v		
21.26-21.28		Additional information on further inputs to its internal reviews		v	
21.29		Initial report called for by paragraph 21.19	v		

*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) The effectiveness of the QMS is ensured by the Management. The management reviews the progress of the quality program, approves documents and discusses quality related issues.

(b) The Quality Manager ensures that the process of continual improvement progresses throughout the Office.

The Quality Manager reports directly to the Director of the ILPO in matters regarding quality of services and the QMS.

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

[The head of each team \(computers and communications, mechanics, physics, medical devices, biotechnology, pharmaceuticals and chemistry\) in the Patent Division is responsible for the quality checking of the national Office Actions and the international reports produced.](#)

Regular 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 issues by meetings, emails and documentation on the ILPO's intranet site.

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 throughout the respective Authority.

A Quality Management Review is held at least once a year according to the Quality Management Standards set out in ISO 9001:2008.

The Board of the ISA/IPEA has been established. This Board meets regularly to discuss issues raised by the substantive patent examiners and PCT formality examiners. The Board includes directors of the Patent Division and PCT Division, deputy director of the Patent Division, ISA/IPEA IT coordinator of the PCT division, quality manager of the ILPO and, the ISA/IPEA quality coordinator. The main goal of the Board is to make sure that there is consistency in the output between the two divisions.

Furthermore, every two weeks, the ISA/IPEA IT coordinator meets with the director of the PCT division to discuss problems encountered in the international reports produced through the automated system (PCT-SAPIA, see Section 21.12 below) 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 21.25-21.28:

- (a) at least once per year (cf. paragraph 21.25);
- (b) in accordance with the minimum scope of such reviews as set out in Section 8, namely:
  - (i) to determine the extent to which the QMS is based on Chapter 21 (cf. paragraphs 21.25, 21.27(a));
  - (ii) to determine the extent to which Search and Examination work complies with PCT Guidelines (cf. paragraphs 21.25, 21.27(a));
- (c) in an objective and transparent way (cf. paragraph 21.25);
- (d) using input including information according to paragraphs 21.27 (b)-(f);
- (e) recording the results (cf. paragraph 21.28).

Executive meetings chaired by the Commissioner (ILPO Director) and attended by all division directors are held each month. 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 ISEA 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 to Sections 21.11 to 21.14, below, should provide this assurance.

21.11 Human resources:

- (a) Provide information about the infrastructure in place to ensure that a quantity of staff:
  - (i) sufficient to deal with the inflow of work;
  - (ii) which maintains the technical qualifications to search and examine in the required technical fields; and
  - (iii) 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.
- (b) Describe the infrastructure in place to ensure that a quantity of appropriately trained/skilled administrative staff is maintained and adapted to changes in workload:
  - (i) at a level to support the technically qualified staff and facilitate the search and examination process;
  - (ii) for the documentation of records.

(a)

The search and substantive examination of international applications are performed by the Patent Division. ~~The number of examiners in~~ In the this division in 2011 increased by 17 and amounted to there are 101 substantive examiners. ~~, of which about 30% of the existing examiners~~ have more than 10 years' experience in their respective fields of science and about 2023% examiners hold Ph.D. degrees. The ILPO examiners have the language skills to comprehend at least those languages in which a minimum documentation is referred to in Rule 34, as well as several others.

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. Additionally, the examiners hold advanced academic degrees in their respective branches of science or technology.

All examiners are fluent in English and Hebrew. Some examiners also have excellent knowledge of German, French, Russian, Spanish, Arabic, Italian, Romanian and Portuguese. All of examiners possess bilingual, and some of them trilingual, capabilities.

New examiners undergo a two-year guided training by a senior examiner, along with lectures from experts. This training program provides the examiners with a broad understanding of patent prosecution and its legal aspects, and enhances their proficiency in performing prior art searches in particular and their competence in examining patent applications in general.

A large number of patent examiners are graduates of prestigious universities such as the Technion, Weizmann Institute and the Hebrew University. Examiners are further encouraged to participate in seminars and courses in their respective technological fields in order to maintain and update their competencies at a high level.

In ensuring the quality of examination work, a central role is played by the continually updated patent examination directives which facilitate staff comprehension of and adherence to quality criteria and high standards.

~~(b)~~

The administrative tasks of the ILPO in its capacity as an International Searching and Examining Authority are performed by the staff of the PCT Division. The staff of this division 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 ~~movement status~~ and workflow, as well as other administrative duties.

The PCT Division has highly skilled and qualified administrative personnel comprising one Division Director, two clerks and 8 PCT formality examiners responsible for PCT work in the Receiving Office, as well as coordinating with ISA/IPEA and designated/elected Office.

~~A new formality examiner was recruited in 2012 and trained in order to support the examination staff and facilitate the international search and examination process.~~

A database manager was appointed to take charge of the support (implementation of updates, new features and training courses provided by the database service suppliers; maintenance and troubleshooting) for the search databases available at the ILPO (see Section 21.12) and of training programs for the substantive examiners organized by the ILPO.

21.12 *Material resources:*

- (a) *Describe the infrastructure in place to ensure that*
  - (i) *appropriate equipment and facilities such as IT hardware and software to support the search and examination process are provided and maintained;*
  - (ii) *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.*
- (b) *Describe how instructions*
  - (i) *to help staff understand and adhere to the quality criteria and standards, and*
  - (ii) *to follow work procedures accurately and consistently*

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

**(a) Material resources infrastructure**

Automated system for processing international applications

In 2012, the ILPO has created a paperless work environment for the formality and substantive examination of national patent 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~~ Concerning international applications, the ILPO has developed a modern and efficient PCT automation system, entitled PCT-SAPIA (System for Administration and Processing of International Applications) to create a paperless work environment in processing ~~international~~

~~applications~~ them at the RO, ISA ~~and IPEA divisions~~ 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 formality 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 Receiving Office and the International Bureau.

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

Furthermore, PCT-SAPIA includes all the checkboxes and text fields of the PCT RO/ISA/IPEA forms of Chapter I and Chapter II of the PCT (for examples: ~~RO/103, 106, 110 & ISA/203, 206, 210, 237, 408, 409, 428, 429~~) and includes ~~an examiner~~ a task list for the substantive, formality and quality examiners, and payment coordinator with built-in reminders to alert ~~examiners~~ them about deadlines.

These reminders come in the form of reports, generated using Business Intelligence (BI) technology, which allow 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;
- processing and sending international search reports and written opinions;
- transmitting withdrawal notifications to WIPO;
- generating lists of international applications (pending).

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

#### Search databases available at the ILPO

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

- Thomson Innovation providing access to core patent collections, Derwent World Patents Index (DWPI), Asian translated patent collections and non-patent literature;
- STN (REGISTRY, CAPIus, BIOSIS, MEDLINE, EMBASE, WPI, INSPEC) providing access to patent and non-patent literature, chemical structure database, and biological sequences database;
- EPOQUE Net providing access to patent and non-patent literature; and
- Questel providing access to core patent collections as well as Asian translated patent collections.

These search databases provide coverage far beyond the minimum documentation requirement of the PCT.

### Technology and Environment employed by the ILPO

The current ILPO system was developed in the Microsoft .Net environment with Client/Server architecture using a Microsoft SQL Server 2008 database.

The ILPO patent examiners are equipped with workstations with the Windows 7 Operating System and the Windows 2008 Server. Each workstation is connected to the Citrix virtual environment and has a CD-ROM drive and Internet access through a high-speed connection. This provides patent examiners with the necessary facilities to conduct their S&E functions.

The ILPO implemented many international standards for improving efficiency, availability, flexibility, scalability and manageability of its systems.

The ILPO's Service Management implements the ITIL Standard (Information Technology Infrastructure Library) 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 contains HP Blade servers that are managed under VMware which provides a completely virtualized set of hardware. Its website operates on a very high data security level, using several firewalls and strict security policy.

### **(b) Documentation of instructions**

The Patent and PCT Divisions 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 \(including, inter alia, circulars from WIPO\)](#) ~~operation—standards,—guidelines,—~~ notifications, ~~rules,—~~ presentations, announcements ~~and circulars from WIPO~~, etc., thus improving the efficiency of the work process.

#### 21.13 *Training resources:*

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

- (i) *acquire and maintain the necessary experience and skills; and*
- (ii) *are fully aware of the importance of complying with the quality criteria and standards.*

### Training resources for ~~S~~substantive ~~E~~examiners

A comprehensive training program for new 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.

New examiners are trained and supervised by a senior examiner for a period of 24 months. ~~The senior examiner has the role of a~~ [Senior examiners, acting as personal tutors for the new examiners, take charge of reviewing and approving the work and reports prepared](#) ~~and is responsible for all decisions made~~ by the new examiners ~~in the processing of an application~~ [throughout the training period](#). During this ~~apprenticeship period~~, new examiners participate in in-house training programs comprising a basic course of 80 hours that imparts

an in-depth insight into the patent processing procedure, including knowledge of various legal aspects of patent law and performing searches. These training programs also confer upon new examiners a broader perspective of the patent, such as the role of patents as an economical tool for enhancing innovation and as a strategic business tool for companies.

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

After concluding the ~~apprentice~~ [two-year training](#) period, examiners can participate in an "extended patent course" of 100 hours organized by the ILPO in conjunction with the patent attorney offices and support of Israeli Universities. The overall idea in this training is continuing the examiners education.

Examiners are authorized to make their own decisions after thorough verification of their competencies and skills. There is an examination at the end of each year during the training period. Upon successful completion of a final exam they are awarded a patent examiner certificate, approved and signed by the Commissioner.

Examiners are encouraged to participate in seminars, [workshops](#) and courses in their respective technological fields, [covering practices in searching, examination and using search databases](#), in order to maintain and update their competencies at a high level. [In addition to the frontal training courses in search databases \(Thomson Innovation, STN, EPOQUE Net and Questel\), examiners are encouraged to participate 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 grant or grant must always be discussed with and approved by a senior examiner.

[In the periodic team meetings of the Patent Division, the substantive examiners raise cases for discussion concerning the substantive examination of the national and international applications. The preannouncements and the summaries of these meetings are posted in the intranet site of the Patent Division and made available to all examiners.](#)

As part of the preparations towards the ILPO becoming an International Searching and Preliminary Examining Authority, substantive examiners took part in a practical initial training pilot (International Search & Examination Pilot – ISEP) in accordance with PCT ~~rules, articles and guidelines~~ [legal texts](#). ILPO examiners prepared simulated search reports and written opinions. The search reports were later compared to the actual reports prepared by the International Search Authority designated by the applicant (USPTO or EPO).

#### [Training resources for the Administrative staff - formality examiners](#)

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

Every new PCT formality examiner undergoes two years of training, beginning with a general course, tutoring and periodic exams.

During this ~~apprenticeship~~ [training period](#), new examiners 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. There is an examination at the end of each year during the training period. Upon successful completion of a final exam they are awarded a PCT formality examiner certificate, approved and signed by the Commissioner.

Only after this period the employee is recognized as a formality examiner and may sign formal paper work without supervision.

The executive formality examiner, ~~acting as has the role of~~ a personal tutor ~~for the new examiners~~ and ~~is responsible for all decisions made~~ takes charge of reviewing and approving the work and reports prepared by the new examiner ~~in the processing of an application~~ throughout the training period.

All employees (new and senior) are updated regularly by the Director of the PCT Division 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 Division holds periodic team meetings for the formality 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 Division.

The PCT division'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.

#### Other training resources

A seminar on studying ISA/IPEA procedures was conducted for ILPO examiners in collaboration with WIPO and the EPO, conducted by representatives of each office.

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 order to learn from their experiences regarding handling international applications.

~~Additional study visits have been scheduled to other patent offices to learn from their experience, including visits to the EPO and NBPR.~~

Trainings and seminars are held on a regular basis for the examiners from the Patent and PCT Divisions. 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:

- examiners workshops;
- in-house special seminars on IP, search and examination;
- EPOQUE-training;
- discussion forums with agents and professional organizations of IP stakeholders, including industry;
- management training.



21.14 Oversight over resources:

*Describe the system in place for continuously monitoring and identifying the resources required:*

- (a) *to deal with demand; and*
- (b) *comply with the quality standards for search and examination*

Division Directors together with the Director of the ILPO are responsible for continuously monitoring and identifying resources required to deal with demand.

### 3. Management of administrative workload

21.15 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:

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

(a) Control mechanisms regarding timely issue of search and examination reports

As ~~was~~ mentioned in 21.11(b), the administrative tasks of this International Searching and Examining Authority 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 ~~movement~~ status and workflow, as well as other administrative duties. These duties are performed by the staff of the PCT Division who have a wealth of previous experience in a wide variety of PCT- related matters.

~~The PCT division has highly skilled and qualified administrative personnel comprising one Division Director, two clerks and 8 PCT formality examiners responsible for PCT work in the Receiving Office, as well as coordinating with ISA/IPEA and designated/elected Offices.~~

~~A new formality examiner was recruited in 2012 and trained in order to support the examination staff and facilitate the international search and examination process.~~

~~The following quality indicators will be established:~~

- ~~• Extent of meeting the time limit for the transmittal of ISRs and WOSAs;~~
- ~~• Extent of meeting the time limit for transmittal of examination demands to the examination divisions;~~
- ~~• Extent of meeting the time limit for the transmittal of IPRP;~~
- ~~• Extent of client satisfaction.~~

~~These reports will be generated using Business Intelligence (BI) technology which allows tracking and monitoring the quality process in its entirety.~~

With respect to ~~the handling of S&E requests and performing related functions~~ all the tasks involved in processing international applications at the RO and ISA/IPEA stages, ~~in the new computerized processing~~ automated system (PCT-SAPIA) provides a quality control assurance mechanism ~~has been implemented to ensure~~ ensuring the timely issuance of international ~~search~~ reports and ~~written opinions~~ communications (see also Section 21.16).

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

~~All Division Directors and Managers~~ The Patent Division and the PCT Division use the Business Intelligence (BI) system for ~~follow-up of applications and for monitoring purposes~~ 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 (a) and (b) can be extracted from the ILPO's IT systems, and reports concerning this information are generated for management.

#### 4. Quality assurance

21.16 *The following are required quality assurance measures for timely issue of search and examination reports of a quality standard in accordance with the Guidelines. Indicate how the following are implemented:*

- (a) *An internal quality assurance system for self assessment, involving verification, validation and monitoring of searches and examination work:*
  - (i) *for compliance with these Search and Examination Guidelines;*
  - (ii) *for channelling feedback to staff.*
- (b) *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.*
- (c) *A system for verifying the effectiveness of actions taken to correct deficient S&E work, eliminate the causes, and to prevent issues from recurring.*

Division Directors are responsible for the control of resources, guiding of work and the uniformity of practices among technical groups in each of their divisions, respectively. The objective is to ensure that S&E of any application leads to the same result irrespective of which team performed the task. ~~One of the resulting measures taken was to upgrade both S&E reports so as to conform to International S&E report formats.~~

~~A special work group has been appointed to develop and support search methods based on the databases at the disposal of the ILPO. Members of this group consist of our most competent examiners, all of who are well acquainted with the use of databases.~~

The PCT Division has ~~appointed one of the senior examiners to be a~~ quality coordinator who is in charge of quality related matters. ~~Every 10th international application is double checked by a different examiner and a report is filled out. This enables the identification of deficiencies in examination and the prevention of their recurrence. This examiner is~~ and also responsible for the control of resources, guiding of work and the uniformity of practices among the formality examiners. The objective is to ensure that processing of an international application leads to the same result irrespective of which formality examiner performed the task.

The staff of the PCT Division 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.

The ILPO has established an internal quality assurance system for ~~100% of the~~ international reports ~~(ISR&WOSA)~~, 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. ~~and the PCT Search and Examination Guidelines and communicating feedback to staff.~~



~~This quality assurance system provides 4 and optionally 5 steps:~~

- ~~1. Automatic quality checking by the automation system;~~
- ~~2. Self-check by the examiner using a checklist, where the most important criteria of quality (known deficits and common errors) are listed;~~
- ~~3. Optional: Cross-check by a second examiner (expert); the cross-check serves as a basis for professional discussions between examiners;~~
- ~~4. Checks by a QA examiner;~~
- ~~5. Final checks by the PCT division.~~

This quality assurance system provides 3 types of checking:

1. Automatic quality checking by the automation system

~~In order to manage a variety of schedules for international search reports (ISRs) and written opinions. As mentioned in Section 21.12,~~ the ILPO has developed a modern and efficient automation system entitled PCT SAPIA (System for Administration and Processing of International Applications) to handle the ~~prosecution processing~~ of international applications electronically and to provide automatic quality checking of the formality examination at the RO stage as well as the formality and substantive examination at the ISA and IPEA stages. This system implements a full scale of automated validations and guidance for the examiner (including warnings for nonconforming cases), thus preventing him from making mistakes and ensuring integrity of the reports, and sends alerts to the division directors in cases where the due dates are not met. This system provides electronic sampling of 100% of the applications.

The business rules implemented in this system are designed ~~to help support~~ ensure the integrity and quality of the ~~Search Reports and Written Opinions~~ international reports produced electronically as well as work efficiency. This is done by guiding the examiner automatically, according to a predetermined work order, and providing warnings (part of which block further processing of the application unless the relevant problem is resolved) in nonconforming cases, preventing him from making mistakes and ensuring integrity of the reports. ~~By this way, the amount of formality and substantive errors in the international reports is minimized and the time needed in preparing the reports is reduced. Thus, PCT examiners minimize errors, which may occur when writing written opinions and search reports, as well as reduce the amount of time spent in establishing of international reports.~~

The family members of the cited patent publications are automatically retrieved by the system. Cited documents (especially those which are not free of charge such as non-patent literature) are uploaded into the system and linked to the relevant citation 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 ~~has an~~ provides examinera -task list for formality, substantive and quality examiners and for the payment coordinator, with built-in reminders to alert them ~~examiners~~ and the administration of ~~an~~ 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 ~~for~~

regarding the applications at hand. These applications are brought to the attention of senior staff members who take the appropriate action.

Active Task List (135)

			Recommended for Closure	Stage	File No.	Task Type	User	Capacity	Due Date
▶	→	☐	⚠	ISA	PCT/IL2012/000294	Perform Substantive Examination	Nissim MA...	ISA Substa...	16 Sep 2012
▶	→	☐	⚠	ISA	PCT/IL2012/050294	Perform Substantive Examination	Emad NIMER	ISA Substa...	16 Sep 2012
▶	→	☐	⚠	ISA	PCT/IL2012/000296	Perform Substantive Examination	Eyal BRODET	ISA Substa...	16 Sep 2012
▶	→	☐	⚠	ISA	PCT/IL2012/050303	Perform Substantive Examination	Emad NIMER	ISA Substa...	16 Sep 2012
▶	→	☐	⚠	ISA	PCT/IL2012/000306	Perform Substantive Examination	Ariel DAVIDI	ISA Substa...	16 Sep 2012
▶	→	☐	⚠	ISA	PCT/IL2012/050334	Perform Substantive Examination	David GRO...	ISA Substa...	16 Sep 2012
▶	→	☐	⚠	ISA	PCT/IB2012/0537...	Perform Substantive Examination	Nimrod Isra...	ISA Substa...	16 Sep 2012
▶	→	☐		RO	PCT/IL2012/000381	Process File - Startformal examination	Yael HALIVA	RO Formalt...	28 Nov 2012
▶	→	☐		RO	PCT/IL2012/050481	Process File - Startformal examination	Yael HALIVA	RO Formalt...	30 Nov 2012
▶	→	☐		RO	2012-050546	Process File - PerformArticle 11(1) ex...	Yael HALIVA	RO Formalt...	29 Nov 2012
▶	→	☐	⚠	ISA	PCT/IL2012/050293	Perform Substantive Examination	Solomon G...	ISA Substan...	02 Oct 2012
▶	→	☐	⚠	ISA	PCT/IL2012/000301	Perform Substantive Examination	Anat HORO...	ISA Substan...	29 Sep 2012
▶	→	☐	⚠	ISA	PCT/IL2012/050319	Perform Substantive Examination	Nicoleta RO...	ISA Substan...	29 Sep 2012
▶	→	☐	⚠	ISA	PCT/IL2012/050330	Perform Substantive Examination	Matan COHAY	ISA Substan...	05 Nov 2012
▶	→	☐	⚠	ISA	PCT/IL2012/000303	Perform Substantive Examination	Elad MOSK...	ISA Substan...	02 Oct 2012
▶	→	☐	⚠	ISA	PCT/IL2012/000302	Perform Substantive Examination	Elad MOSK...	ISA Substan...	02 Oct 2012
▶	→	☐	⚠	ISA	PCT/IL2012/050315	Perform Substantive Examination	Yelena GOR...	ISA Substan...	02 Oct 2012

To help examiners prepare ISR&WOSA more efficiently, written opinion samples have been collected and the most frequently used clauses in the written opinions have been made available to the examiners.

## 2. Self-checking by the examiner

The formality and substantive examiners fill out checklists for each international application covering the steps to be completed at the RO and ISA stages.

## 3. Checking by the QA examiner and by a second examiner

3.1. At the RO stage, 10% of the filed international applications are cross-checked by a second RO formality examiner. The checking covers formality issues such as bibliographical details, contents of the application and physical requirements under Rule 11.

3.2. At the ISA/IPEA stage, three kinds of checking are performed:

3.2.1. Substantive examination checking: The quality examiner checks 100% of the international reports covering mainly issues related to novelty, inventive step and lack of unity of invention. 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.

3.2.2. ISA/IPEA formality examination checking: The ISA formality examiner performs a formality checking on all PCT forms (100% sampling) to be sent to the applicant and IB, inspecting the integrity and consistency of the details in the forms.

3.2.3. Periodic audit of a random sample of cases: Approximately 25% of the PCT forms of the international applications designating the ILPO as ISA are cross-checked by a second ISA formality examiner, using a quality assurance checklist. Audit findings and recommendations are recorded in the automation system.

### **Check-lists to verify the quality of issued reports**

~~Check Lists are used for Search strategies, Search reports, and Written Opinions.~~

~~In addition, to implement Quality Control, Quality Metrics, covering all processing stages of the international application, have been set for the examiners.~~

~~All examiners have online access to interlinked PCT guidelines, PCT regulations and work manuals for the different steps of the search and examination process.~~

## **5. Communication**

### *21.17 Inter-Authority communication:*

*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, patent examiner and Quality Manager: [MosheCo@justice.gov.il](mailto:MosheCo@justice.gov.il)

Dr. Imad Zakharia, patent examiner: [ImadZ@justice.gov.il](mailto:ImadZ@justice.gov.il)

[Israel Patent office](#)  
[Malcha Technology Park, Building 5](#)  
[1 Agudat Sport Hapoel St.](#)  
[Jerusalem 96951](#)  
[Israel](#)

[Facsimile No. 972-2-5651616](#)

**21.18 Communication and guidance to users:**

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

- (a) *An appropriate system for
  - (i) *handling complaints and making corrections;*
  - (ii) *taking corrective and/or preventative action where appropriate; and*
  - (iii) *offering feedback to users.**
- (b) *A procedure for:
  - (i) *monitoring user satisfaction and perception; and*
  - (ii) *for ensuring their legitimate needs and expectations are met.**
- (c) *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.*
- (d) *An indication of 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:

(a) 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.

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

(b) [Customer feedback](#)

The ILPO conducts a satisfaction survey of customers on an annual basis. This survey addresses quality and other customer satisfaction parameters for [national and international](#) patent applications ~~and PCT international applications~~. The results of customer surveys are evaluated and taken into consideration for possible future amendments to ILPO internal guidelines.

In addition, the ILPO has a client feedback mechanism in place for filed applications. Client feedback is always checked thoroughly and any action that may be warranted is taken, be it corrective or preventive. In this vein, we have put in place a mechanism that includes meeting with representatives from both local industry and patent attorney firms periodically to discuss quality related issues.

[A PCT Help Desk is functioning as of 2012 and handles customer complaints, providing customers with assistance on a wide variety of PCT matters.](#)

(c) Guidance and information for users

The PCT division provides guidance and information for users by:

- Face-to-face communication (helping and advising how to file international applications);
- Holding PCT seminars;
- Roundtables (upon request);
- Providing informative material on the [ILPO Website](#).

On the ILPO website, general information is given on filing international applications with a link to the WIPO website, concerning PCT prosecution.

Different communication channels have been made available to applicants and their agents including a personal visit to the Office, telephone, fax and email.

The ILPO PCT Division which is highly regarded both nationally and internationally is very supportive of applicants who need to deal with the complexities of filing their PCT applications in both the international and national phases.

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

*21.19 Communication with WIPO and designated and elected Offices:*

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

Communication with WIPO and designated and elected offices is done through the PCT division. This division 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 division 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 division 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 applications.

[In 2013 the ILPO PCT division started using ePCT services for downloading "post-filing" documents in electronic form.](#)

## 6. Documentation

21.20 *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 in the documents that make up the Quality Manual of the Authority (see paragraph 21.21).*

*(Note: This point is informative. No response is required by the template to paragraph 21.20)*

21.21 *The documents that make up the Quality Manual serve to document the procedures and processes affecting the quality of work, such as classification, search, examination and related administrative work. In particular, the Quality Manual indicates where to find instructions on the procedures to be followed.*

*For the purposes of this report indicate:*

- (a) the documents making up a Quality Manual that have been prepared and distributed;*
- (b) the media on which it is 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 ~~q~~Quality and ~~w~~Work ~~instructions- Manuals~~ for each division of the ILPO (~~including the Patent Division and the PCT Division~~) are made available to the staff. Any ~~alteration to the quality documents~~ update in the contents of the manuals is brought to the relevant division director for approval. Upon approval of any such ~~alteration to any such document~~ update, the version number of the ~~edition of the relevant~~ document is ~~altered~~ updated and distributed to all staff in the ~~appropriate department~~ relevant division, and ~~the document is updated in the internal information network~~ published on the intranet site of that division. Documents belonging to previous ~~editions-versions~~ are kept for follow up purposes.

21.22 *Indicate whether the documents making up the Quality Manual include the following:*

- (a) the quality policy of the Authority including a clear statement of commitment to the QMS from top management;*
- (b) the scope of the QMS, including details of and justification for any exclusions;*
- (c) the organizational structure of the Authority and the responsibilities of each of its departments;*
- (d) 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;*
- (e) the resources available for carrying out the processes and implementing the procedures; and*
- (f) a description of the interaction between the processes and the procedures of the QMS.*

The ~~quality handbook~~ Quality Manual contains ~~a document that~~ includes the quality policy of the ILPO, ~~as well as~~ the organizational structure of the ILPO, ~~and all~~ All the Instructions and procedures for the ongoing operation of the Quality Management System (QMS) ~~are set forth in the documents of the quality procedures and work instructions.~~

The ILPO has resources for the implementation of all the quality requirements as they appear in the above mentioned ~~documents~~ Manual.

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 procedures and work instructions are being fulfilled.

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

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

- (a) a definition of which documents are kept and where they are kept;
- (b) results of management review;
- (c) training, skills and experience of personnel;
- (d) evidence of conformity of processes, resulting products and services in terms of quality standards;
- (e) results of reviews of requirements relating to products;
- (f) the search and examination processes carried out on each application;
- (g) data allowing individual work to be tracked and traced;
- (h) records of QMS audits;
- (i) actions taken re. non-conforming products, e.g. examples of corrections;
- (j) actions taken re. corrective action;
- (k) actions taken re. preventative action; and
- (l) search process documentation as set out in Section 7.

In accordance with ISO 9001 standard the ILPO stores and maintains the following documents:

- a ~~Quality handbook~~ Manual;
- Work Manual (including quality work procedures and ~~work~~ instructions);
- results of management reviews;
- records about training;
- skills and experience of staff;
- evidence of conformity to processes;
- results of reviews of requirements relating to products;
- records on corrective or preventive actions;
- records on actions taken concerning non-conforming products;
- records of QMS audits;
- records of the search and examination process carried out on each application.

## 7. Search process documentation

21.24 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:
  - (i) limitation of search and its justification
  - (ii) lack of clarity of the claims; and
  - (iii) lack of unity.

(a) – (c)

The search process documentation for each Search/Examination 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, 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

21.25 *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.*

21.26-21.28 *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*



~~The ILPO has implemented all parts of the QMS.~~

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. ~~along with external audits that take place annually as well, in order to achieve and maintain ISO 9001 certification.~~ These reviews are presented to top management at management reviews.

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**

*21.29 There are two stages in the reporting arrangements. The document up to this point relates to the initial report called for by paragraph 21.29. It will be supplemented annually by further reports in accordance with paragraph 21.30.*

[End of document]