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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 2024

Human resources

• Al Implementation Team

An AI Implementation Team has been formed to integrate artificial intelligence (AI) tools into the substantive examination of published patent applications. This team is responsible for analyzing authorized AI tools, implementing them in the examination process, monitoring their use, and conducting ongoing AI technology research for continuous improvement.

• ILPO Innovation Hub

As part of a new initiative to enhance the ILPO's role within the public sector and improve Israel's global position in intellectual property, a team led by the Information & Database Manager has been formed. This team focuses on utilizing existing resources and services to improve the quality and variety of services provided to applicants.

Material resources

• Preparations for adhering to PCT Rules 36.1(ii) and 63.1(ii) effective from 1/1/2026

- The IL Authority File has been prepared, according to Standard ST. 37 Version 2.2, covering the patent data since 01 January 1991.
- While the patent data is already available in text-searchable format on the ILPO website, further validation was conducted to ensure that all patent documents, published since 01 January 1991, are available in text-searchable format.
- Preparations are underway for making available all the national patent documents, published since 01 January 1991, in bulk format electronically to any requesting Office.

• Al implementation in examination processes

- A new Al-based search tool, supporting free-text and image searches, has been provided to patent examiners. A further Al tool is integrated for prompt-based analysis of the full-text of the search results.
- A pilot has been successfully launched to implement Al during all stages of the substantive examination of published patent applications. This pilot includes the following functions:
 - analyzing applications to summarize the invention, identify the problem to be solved and the essential features representing the solution, and assess compliance with clarity and support requirements;
 - developing and using AI bots to examine the prior-art documents in relation to the claimed invention;
 - developing and using AI bots to assess compliance of the application with the examination guidelines;
 - creating prompts for the continued substantive examination to evaluate the applicant's response in relation to the objections raised in the Office Action;
 - conducting a quality review before acceptance, including an assessment of prior-art documents cited by foreign offices in relation to the latest claim set.

Upgrade of the e-filing system for national applications

- o <u>The Patents Journal has been upgraded to allow downloading of the published application documents.</u>
- The e-filing system for national applications now supports English. Additionally, a smart request-filing module has been developed, supporting Hebrew and English. The module displays only relevant requests based on the application's status and stage, with pertinent notifications and warnings. This enhances efficiency and accuracy in request submission. The system will launch in Q1 2025.

Comparative analysis of cited prior art

- The ILPO continued its participation in the ISR feedback pilot led by the UK IPO, where national offices provide feedback on the ISRs issued by ISAs for applications entering the national phase. Feedback was received from the national offices, and measures for improvement were implemented.
- A pilot program has been established to compare search results from ISAs other than the ILPO with those established by the ILPO for corresponding accelerated applications first filed in Israel.

Preliminary search service

A new service has been launched in collaboration with the Israel Innovation Authority to provide preliminary search service for entrepreneurs. This service includes a meeting with the entrepreneurs, during which a prior-art search is conducted based on the inventive concept described. Additionally, relevant information concerning intellectual property aspects and patent application examination routes is explained. Service recipients have expressed satisfaction with the overall quality of the service.

Updates to the Examination Guidelines and Work Instructions

- A new draft of the Examination Guidelines has been prepared including updates relating to:
 - the novelty of claimed inventions relating to products used in the medical treatment of sub-populations;
 - o antibodies; and
 - o the examination process of applications for extension orders.
- Internal instructions have been formulated regarding the examination of claims relating to the homology of biological sequences.
- Work instructions have been prepared regarding risk management under ISO 31000 (Risk management – Guidelines) and ISO/IEC 23894:2023 (Information technology – Artificial intelligence – Guidance on risk management).

Research activities

- A research study was conducted by a patent examiner, who is a candidate for senior examiner, to investigate the capability of AI tools in decision-making during the substantive examination of patent applications. The study involved integrating a selected AI tool into the examination process, assessing its ability to determine novelty and inventive step of the claimed invention in view of the prior art, and developing general prompts to support substantive examination. Additionally, the study included the development of reasoning through continued examination. The AI tool used in the study demonstrated a 93% success rate in making correct decisions and was found to be useful in analyzing complex and interdisciplinary inventions.
- A study was conducted by the PCT Department for identifying key characteristics regarding international applications requesting examination under Chapter II of the PCT. Analysis was conducted starting from the ISA stage throughout the IPEA stage, collecting data related to the amendments made and to the way it was examined. It was concluded that a demand under Chapter II of the PCT is an effective tool for obtaining a positive report in the international phase and an excellent opportunity to amend the application while clarifying issues with the examiner.

Quality standards

- In light of the Al advancements at the ILPO and following the compliance of the risk-based practices with the guidelines of ISO 31000, preparations are underway to align the QMS with ISO/IEC 23894:2023 (Information technology Artificial intelligence Guidance on risk management).
- The ISO 9001:2015 certification, covering all the functions of the ILPO, was extended to 2025.

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, granting it independence in several areas. The ILPO is responsible for registering patents, designs, trademarks and appellations of origin, thereby ensuring adequate legal protection for industrial intellectual property in Israel. This is obtained through 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, as an ISA/IPEA, conducts search and examination in all technical fields, even those not required by PCT Rules 39 and 67 or not patentable under Israel Patents Law, like therapeutic treatment methods and business methods. The ISRs are accompanied by search strategy reports with listings of search statements. In cases where there is a lack of unity of invention, a partial search report concerning the first invention is sent to the applicant along with Form PCT/ISA/206.

The ILPO's diversity promotion policy among human resources has facilitated the recruitment of highly-qualified examiners who are proficient in a variety of languages and possess advanced degrees in various technical fields, including sciences, engineering, and medicine.

The ILPO signed PPH and PCT-PPH agreements with multiple Patent Offices and joined GPPH to enhance international work sharing and improve patent examination quality.

The ILPO launched the "PCT Direct" service in April 2015 to enhance the efficiency and quality of PCT application examinations, following the EPO's implementation in November 2014.

In 2010, the ILPO was the first unit in the Ministry of Justice to implement a teleworking project, starting with examiners working outside Jerusalem, which was later extended to all examiners in the PCT and Patents Departments who can work till 50% of the working hours from home.

In 2012, the ILPO created a paperless work environment for the formalities and substantive examination of national and international patent applications. In the same year, a PCT e-filing system was launched, by which all the PCT applications are filed with the RO/IL.

In 2015, an e-filing system was launched for national patent applications, by which almost all the national applications (>99%) are filed.

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, PCT applications, 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 (PCT/GL/ISPE). Furthermore, the ILPO implements risk-based practices in accordance with ISO 31000 principles, and preparations are underway to align the QMS with ISO/IEC 23894:2023 (Information technology - Artificial intelligence - Guidance on risk management).

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 specified by top management.
- (c) An organizational chart showing all those bodies and individuals responsible for the QMS.
- (a) The ILPO Quality Manual includes the quality policy, the bodies and individuals responsible for the QMS and an organizational chart showing them. This manual is available on the department homepages of the ILPO intranet.

A Service Level Agreement (SLA) is in place for the services provided by ILPO departments (Patents Department, Patents Administration, PCT Department, Industrial Designs Department, Trademarks Department and Legal Department). It defines the time frames for the processing of applications during the formalities and substantive examination stages.

The ILPO views service quality as important for improving efficiency and necessary for its integration into the international community through treaties that require adherence to high-level quality standards, such as the Madrid Protocol and the PCT. Regarding the latter, the ILPO, in its capacity as an ISA/IPEA, is committed to processing international patent applications according to the PCT Regulations, PCT Administrative Instructions (PCT/AI), the PCT Receiving Office Guidelines (PCT/GL/RO), the PCT International Search and Examination Guidelines (PCT/GL/ISPE) and the internal instructions. The ILPO's QMS is ISO 9001:2015 certified, covering all services, including national and international patent applications processing.

Please see also Section 7 below (under paragraphs 21.22-21.24).

(b) The bodies and individuals involved in the QMS are presented in the ILPO organizational chart below (highlighted in green).

The Director of the ILPO is responsible for the QMS.

The following officers are directly involved in the implementation of the QMS:

 The Quality Manager, as defined in ISO 9001:2015, oversees the day-to-day implementation and continuous improvement of the QMS. He reports on its functionality and recommends improvements to top management.

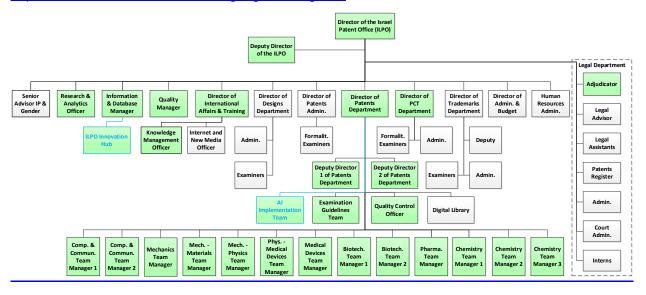
The main functions of the Quality Manager are:

- planning, coordinating, and implementing the quality policy;
- promoting and coordinating the preparation and update of standards and procedures;
- o promoting and coordinating certification of all ILPO activities according to ISO 9001;
- ensuring establishment and implementation of QMS procedures according to the requirements of ISO 9001:2015, PCT Regulations and PCT/GL/ISPE (Chapter 21);
- developing, distributing, reviewing, and updating the Quality Manual;
- o performing controls to validate the implementation of quality policy;
- ensuring that deadlines and objectives are met;
- proposing, coordinating, and supervising surveys among users; and
- o providing data for external audits.

- The Team Managers for each technical field (computers & communications, mechanics, mechanics-materials, mechanics-physics, physics-medical devices, medical devices, biotechnology, pharmaceutics, and chemistry) in the Patents Department are responsible for the quality control of the national Office Actions and the international reports produced. The Team Managers conduct semiannual evaluations for the examiners and are responsible for their professional development.
- The Quality Control Officer in the Patents Department is responsible for quality checking national patent application examinations, updating Examination Guidelines and Standardized Clauses, managing the BI system, and providing productivity and quality reports. These reports include statistics on examinations by stage and route, as well as data on examination efficiency, timeliness, and evaluations by Team Managers.

(c) ILPO organizational chart

In the following organization chart of the ILPO, the bodies and individuals involved in the implementation of the QMS are highlighted in green.



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			
				fu	II	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	,	/		

Chapter 21 requirement			Extent of compliance			
				full	part	no
		(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	✓		
		(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 search and examination (S&E) complies with PCT Guidelines	✓		
		(c)	an objective and transparent way	✓		
		(d)	using input incl. information according paragraph 21.29	✓		
		(e)	recording the results	✓		
21.10			Risk and opportunities are addressed that can affect the QMS and the conformity of search and examination	✓		
21.13			Arrangements for establishing risk-based practices to	✓		
	(i)	(a)	understand issues that affect its ability to achieve intended results of the QMS	✓		
		(b)	understand the needs and expectations of interested parties	✓		
	(ii)		identify risks and opportunities related to the performance of the QMS as a basis for planning	✓		
	(iii)		plan and implement actions to address risks and opportunities	✓		
	(iv)		check the effectiveness of the actions taken	✓		
	(v)		continuously update risks and opportunities.	✓		
21.15			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	✓		

Chapte	er 21 i	requi	rement	Extent of compliance		e
				full	part	no
		(a)	at a level to support the technically qualified staff	✓		
		(b)	for the documentation of 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	✓		
21.16	(i)		Control mechanisms to ensure timely issue of S&E reports	✓		
	(ii)		Control mechanisms regarding fluctuations in demand and backlog	✓		
21.17	(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, eliminate the causes and prevent issues from recurring	✓		
21.19		(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	✓		
21.20	(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	✓		

I I			Extent of compliance			
				full	part	no
		(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	✓		
21.21			Established communication with WIPO and designated and elected Offices	✓		
21.22			QMS of Authority clearly described and documented	✓		
21.23		(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	✓		
21.24			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	✓		
	(iv)		Documented processes carried out in the Authority	✓		
	(v)		Resources available to carry out processes and implementing the procedures	✓		
	(vi)		Description of the interaction between the processes and the procedures of the QMS.	✓		
21.25	(i)		Records of 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)		Records of evidence of conformity of processes, resulting products and services in terms of quality standards	✓		
	(v)		Records of results of reviews of requirements relating to products	✓		
	(vi)		Records of the S&E process carried out on each application	✓		
	(vii)		Records of data allowing individual work to be tracked	✓		
	(viii)		Records of QMS audits	✓		
	(ix)		Records on actions taken re. non-conforming products	✓		
	(x)		Records on actions taken re. corrective actions	✓		

Chapter 21 requirement				Extent of compliance		
			full	part	no	
	(xi)	Records on actions taken re. preventive actions	✓			
	(xii)	Records referring to search process documentation	✓			
21.26	(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	✓			
21.27		Report on its own internal review processes	✓			
21.28- 21.30		Additional information on further inputs to its internal reviews	✓			
21.31		Initial report called for by paragraph 21.31	✓			

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

Management ensures the effectiveness of the QMS through semiannual reviews with the Director of the ILPO, Director of the Patents Department, Quality Manager, and Quality Control Officer. These reviews evaluate compliance with the SLA and quality objectives, while addressing findings from quality reviews, court decisions, customer feedback, and IP representatives' roundtables. Additionally, Management establishes new annual goals and sets detailed quarterly tasks.

The Director of the Patents Department holds monthly meetings with the Quality Control Officer to review the findings of the quality checks, after which decisions are taken to address non-conforming cases and plans for improvement.

The Director of the Patents Department meets regularly with the Team Managers to discuss quality-related matters related to each team.

(b) Continual improvement progress

The Quality Manager oversees continual improvement within the Office and reports to the Director of the ILPO on the quality of services, using data and feedback from Directors of Departments, Team Managers, examiners, and customers. The Quality Manager also receives feedback from external auditors to maintain ISO 9001 compliance.

The Examination Guidelines Team is responsible for updating the Examination Guidelines and analyzing feedback from both examiners and the public. After approval, changes are communicated through email or staff meetings. Training is provided if necessary.

Team Managers in the Patents Department are responsible for the quality control of the national Office Actions and the international reports produced. They collect data on the percentage of citations in foreign national/regional phases that originate from ISRs of the ILPO.

The Quality Control Officer takes charge of the quality checking of the substantive examination of national patent applications, updating the Examination Guidelines and national Standardized Clauses, managing the Business Intelligence (BI) system, and providing productivity and quality reports to each examiner as well as to Management.

The Knowledge Management Officer takes charge of identifying, extracting, preserving knowledge assets, and making them available for all ILPO staff.

The Research & Analytics Officer leads research activities that support ILPO's policy, including initiating, implementing, promoting, and presenting studies. The officer also collaborates with various local and international parties on research projects.

Management implements an incentive program for the examiners to improve the examination quality and efficiency, and maintain compliance with the service level agreement.

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 management applies several mechanisms to communicate to the staff the importance of meeting treaty and regulatory requirements, including:

- sending instructions and clarifications by email and/or documenting them on the intranet;
- checking compliance ILPO Examination Guidelines, PCT/GL/ISPE, and internal instructions;
- providing automated systems with guided work environment including alerts and notifications;
- meetings with all patent examiners;
- team meetings;
- semiannual personal evaluation meetings for each examiner;
- setting goals for each examiner depending on seniority;
- assigning tasks to staff with specified due dates in the automated systems; and
- providing productivity and quality reports to each examiner.

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 twice a year according to the Quality Management Standards set out in ISO 9001:2015 (please refer to paragraph 21.06(a) above).

The ISA/IPEA Board consists of Directors and Deputy Directors from the Patents and PCT Departments, the ISA/IPEA IT Coordinator, Quality Manager, Quality Control Officer, and PCT Quality Coordinator. Its main goal is to ensure consistent output between the departments. The Board addresses international work issues, monitors operations through formalities, and substantive examination, and reviews nonconformities from departmental transactions. It also evaluates potential changes to the internal automated system for processing PCT applications (PCT-SAPIA) (see Material resources under paragraph 21.15). Regular meetings are held to discuss issues raised by substantive patent examiners and PCT formalities examiners.

The ISA/IPEA IT Coordinator meets regularly with the Director of the PCT Department to discuss technical issues with PCT-SAPIA. Suggested improvements are 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 21.27-21.30:

- (a) at least once per year (cf. paragraph 21.27);
- (b) in accordance with the minimum scope of such reviews as set out in Section 9, namely: to determine the extent to which the QMS is based on Chapter 21 (cf. paragraphs 21.27, 21.29(i)); to determine the extent to which Search and Examination work complies with PCT Guidelines (cf. paragraphs 21.27, 21.29(i));
- (c) in an objective and transparent way (cf. paragraph 21.27);
- (d) using input including information according to paragraphs 21.29 (ii)-(vi);
- (e) recording the results (cf. paragraph 21.30).

A Quality Management Review is held twice a year according to the Quality Management Standards set out in ISO 9001:2015 (please refer to paragraph 21.06(a) above).

Executive meetings chaired by the Director of the ILPO and attended by all Directors of Departments are regularly held. During these meetings QM issues are reviewed, the availability of appropriate resources is discussed, and necessary steps are taken to ensure remedies as needed. Furthermore, the summary of the meetings, including the results and decisions made, are maintained in an internal documentation system.

21.10 Indicate whether top management of the Authority promote practices to ensure that risks and opportunities that can affect its QMS and the conformity of international search and examination are addressed.

Top management ensures that risks and opportunities affecting the QMS and international search and examination conformity are addressed, as described in section 2 below. These practices comply with ISO 9001:2015 and ISO 31000 guidelines, allowing the ILPO to publish an SLA for its services, including search and examination.

2. RISK-BASED PRACTICES

21.11 Explanatory note: Each Authority should establish its own risk-based practices to enable the Authority to determine factors that could cause operational processes and its quality management system to deviate from requirements or planned results, to put in pace preventive controls to minimize negative effects, and to make use of opportunities as they arise.

21.12 Explanatory note: It is open to each Authority to set up its own arrangements to determine the effect of uncertainty on objectives. Paragraph 21.13 provides a guide to the basic components of risk-based practices as an element of QMS. There is no requirement for formal methods of risk management or a documented risk management process.

(Note: These points are informative. No response is required by the template to paragraphs 21.11 and 21.12).

21.13 Arrangements for establishing risk-based practices

Provide information on the arrangements that your Authority has made to:

- (i) (a) understand issues that affect its ability to achieve intended results of the QMS, and
 - (b) understand the needs and expectations of interested parties;
- (ii) identify risks and opportunities related to the performance of the QMS as a basis for planning;
- (iii) plan and implement actions to address risks and opportunities;
- (iv) check the effectiveness of the actions taken; and
- (v) continuously update risks and opportunities.
- 21.14 Explanatory note: All processes of the QMS present differing levels of risk in terms of the Authority's ability to meet its objectives, and the effects of uncertainty are not the same for all Authorities. Each Authority is responsible for the actions it decides to take to address risks and opportunities.

(Note: This point is informative. No response is required by the template to paragraph 21.14).

The ILPO implements risk-based practices in accordance with ISO 31000 principles, <u>and preparations are underway to align the QMS with ISO/IEC 23894:2023 (Information technology - Artificial intelligence - Guidance on risk management).</u>

The ILPO has set up several mechanisms for understanding the issues affecting the ability to achieve the intended results of the QMS and the needs and expectations of interested parties, identifying risks and opportunities related to the performance of the QMS, and planning and implementing actions to address the risks and opportunities. These mechanisms include:

- A risk evaluation mechanism is used for current and future aspects (e.g., services, policies, positions). Each aspect's data is recorded in a table with a list of parameters such as: risks, opportunities, likelihood, impact level, significance (impact level multiplied by likelihood), ways for risk mitigation / implementing opportunities, actions required, person(s) in charge, desired goals and the actual results. Decisions are based on the results of the risk-based analysis.
- Several resources are used to collect risk-related feedback, discuss the availability of suitable resources, and implement the necessary actions. These resources include the following:
 - o Internal executive meetings: semiannual management reviews (see paragraph 21.06(a) above); regular executive meetings attended by the Director of the ILPO with all the Directors of Departments; annual strategic planning meetings, attended by the Director of the ILPO, all Directors of Departments, Team Managers, Research & Analytics Officer and representative of the Planning and Strategy Division of the Ministry of Justice;

- Management meetings with external parties: regular meetings between the Director of the ILPO, Directors Departments and Israeli IP professional associations; and roundtables held by the PCT and Patents Departments with ILPO services' users;
- o study visits to industry and academic institutions;
- o public feedback on updates in Examination Guidelines and Commissioner Circulars;
- results of quality checks: internal reviews by the Team Managers and the Quality Control Officer, and external audits to ensure continuous compliance with ISO 9001;
- quality surveys: internal surveys communicated to the ILPO staff and external surveys communicated to users of the ILPO services;
- o analytics data provided by the business intelligence (BI) system;
- o reports on characteristics of ISRs prepared by the International Bureau; and
- comparative analysis of search results from other Offices.
- A dedicated team, known as the ILPO Innovation Hub, has been formed to leverage existing
 resources and services to enhance the quality and diversity of services provided to applicants.
 This team engages in discussions that address the needs and expectations of stakeholders.

Department Directors, in coordination with the Team Managers and Quality Control Officer, conduct follow-ups on the effectiveness of the actions taken by the ILPO. The outcomes of the decisions and changes are continuously analyzed to ensure that risks are properly addressed.

The outcomes of the quality assurance measures (see paragraph 21.17), the different feedback resources (see paragraph 21.20), and the research activities done at the ILPO, are used for the continuous update of risks and opportunities.

3. RESOURCES

21.15 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 130-140 full-time substantive examiners holding

advanced degrees in science, engineering, human and veterinary medicine, where most of them hold master's degrees and about 24% of them hold Ph.D. degrees. About 50% of the examiners have more than 10 years' experience in their respective technical fields. They have the language skills to comprehend at least those languages meeting the minimum documentation requirement under PCT Rule 34. Some examiners also have mother-language level of Arabic, Russian, French, Ukrainian, Amharic, Romanian, Spanish, Italian, German and Portuguese. All examiners possess bilingual, and some of them trilingual or quadrilingual capabilities.

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;
- Optionally, an expert examiner, who works together with the substantive examiner, especially in cases involving multidisciplinary fields; and
- Team Managers (acting as quality control reviewers) 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.

A project is in place to facilitate the mobility of examiners between teams in related technical fields, aiming to enhance proficiency, address occupational burnout, and improve teamwork.

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. The Team Managers conduct semiannual evaluations for the examiners and oversee their professional development.

Formalities examiners

The administrative tasks of the ILPO in its capacity as an ISA/IPEA are performed by the staff of the PCT Department who have gained extensive experience in all PCT-related proceedings.

The PCT Department has highly skilled and qualified administrative personnel comprising the Director, one clerk and 7 PCT formalities examiners responsible for PCT work in the RO, ISA/IPEA and the designated/elected Office. All of the formalities examiners have at least a Bachelor's degree and most of them hold a Master's degree in law, science and engineering.

Information & Database Manager

The Information & Database Manager is responsible for maintaining compliance with the PCT Minimum Documentation requirements, updating the IL Authority File, and sharing the national patent collection with other offices upon request. This role also involves providing support, training and follow-up on most advanced features regarding the search databases available to the ILPO examiners (see "Material resources" below) as well as the implementation of CPC updates.

Al Implementation Team

An AI Implementation Team has been formed to integrate artificial intelligence (AI) tools into the substantive examination of published patent applications. This team is responsible for analyzing suitable authorized AI tools, implementing them in the examination process, monitoring their use, and conducting ongoing AI technology research for continuous improvement.

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

The ILPO maintains advanced automated systems supporting a paperless work environment for the formalities and substantive examination of national and international applications.

Automated system for national patent applications

The automated system for national applications stores documents, manages communications, and generates patent data for transmission to other offices. It offers a guided work environment (with standardized clauses in Hebrew and English) and documents structured data like citations, CPC codes, and objections.

Automated system for PCT applications

The PCT applications are processed during the RO, ISA, and IPEA stages by PCT-SAPIA automated system, which offers a structured work environment. After selecting the appropriate checkboxes and completing the necessary text fields in the system, the PCT forms are generated automatically in PDF format and XML format per WIPO Standard ST. 96. The system includes a task list for the substantive, formalities and quality reviewers, and payment coordinator with built-in alerts. It performs automated validations (including fees) and secure online communications with applicants and WIPO via PCT-EDI.

o Business Intelligence (BI) system

ILPO Management utilizes a BI system to analyze international applications, monitor the workload of each examiner and team, and track fluctuations in demand and backlog.

Automated allocation mechanism

The internal automated systems include an automatic allocation mechanism to improve the allocation of applications to examiners, considering their workload and seniority.

E-filing systems

- All the PCT applications and most of the national applications (>99%) are filed online.
- The e-filing systems for national and PCT applications use Glassbox analytics to visualize customer behavior in real time. With customer consent, it records, indexes, and analyzes digital interactions, providing insights that help the ILPO improve system quality and efficiency.
- For applications filed from July 1, 2022, the sequence listings are accepted only in XML format according to WIPO Standard ST. 26.

• Search databases available at the ILPO

Five advanced commercial search databases are available for all examiners, each of which supporting patent (with full-text machine translations) and non-patent literature (NPL) search:

- Derwent Innovation, additionally including Derwent World Patents Index (DWPI), Derwent Patent Citations Index (DPCI), and Asian translated patent collections;
- o STN, additionally including chemical structure and biological sequences databases;
- Reaxys, supported by AI technology, for searching chemical reactions, chemical structures and substance properties;
- Orbit Intelligence (FamPat); and
- PatBase.

These search databases provide coverage fully complying with the minimum documentation requirement of the PCT. NPL full-text documents can be ordered upon need.

In addition to the five commercial databases, the national collection can be searched via the internal automated system for national applications and on the ILPO's internet website. Furthermore, a new Al-based search tool has been made available to the examiners. This tool supports free-text and image searches, with an integrated Al feature for prompt-based analysis of the of the search results. It is also used in the allocation of patent applications. The use of Al in prior-art search is indicated in the search strategy accompanying the ISR.

• Information exchange and cooperation with other Offices

- o Data exchange with WIPO and other offices
 - The ILPO utilizes the PCT Electronic Data Interchange (PCT-EDI) system for communications with WIPO concerning both international and national applications. The ILPO provides WIPO monthly updates on national phase entry in XML format.
 - The ILPO regularly uses the eSearchCopy system for international applications filed by US applicants with the RO/US and by Israeli applicants with the RO/IB, for which the ILPO is a competent ISA. Once received via secure FTP protocol, the international applications are automatically uploaded to the PCT-SAPIA for further processing.
- WIPO Centralized Access to Search and Examination (CASE)
 The ILPO participates in the WIPO CASE system as an Accessing and Providing Office.
- WIPO Digital Access Service (DAS)
 The ILPO participates in WIPO DAS as an Accessing and Depositing Office.
- Patent Prosecution Highway (PPH) arrangements

To enhance international collaboration and examination efficiency, the ILPO has PPH arrangements with several Offices, as well as PCT-PPH and Global PPH arrangements.

Implementation of Cooperative Patent Classification (CPC) system
 The ILPO classifies PCT applications and national applications first filed in Israel according to CPC. The USPTO provides CPC classifications for international applications entering the national phase in Israel based on an agreement.

Technology and Environment employed by the ILPO

o Workstations

The ILPO patent examiners use workstations with access to the internal automated systems, and to high-speed internet. Each workstation has two computer monitors. This setup provides the necessary tools to perform the S&E tasks effectively.

o Teleworking

All substantive and formalities examiners can work up to 50% of their working hours from home. Examiners of the same team select certain days of the week on which all of them are present at the Office.

Intranet

The ILPO's intranet provides a wide range of documents, tools and information including: national and PCT legal texts; internal instructions; links to databases; Quality Manual; notifications about events; training materials; best practices shared by examiners; suggestion box; and editing tools.

Information technology infrastructure

The ILPO's Service Management implements the Information Technology Infrastructure Library (ITIL) Standard. 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 their own homepages set up on the ILPO intranet. Each homepage includes up-to-date Work Instructions (including, the Examination Guidelines of patent applications in English and Hebrew), PCT legal texts, and communications (e.g., circulars from WIPO), notifications, presentations, announcements, etc., thus improving the work efficiency.

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. Further updates are included in amended versions of the same two circulars.

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

The ILPO has a 24-month training program for new patent examiners, including mentorship by senior examiners. Trainees attend an in-house course covering legal and practical aspects of patent prosecution, providing a thorough understanding of the patent system and its role in innovation and business strategy. At the end of each year, they undertake a theoretical exam (in legal aspects and practice) and a practical exam (examining a patent application). After passing the final exams, they are entitled to sign search and examination reports under close supervision for another year, during which they are encouraged to exercise their judgment.

All substantive patent examiners

o Regular training programs

Patent examiners stay updated on changes in patent legislation, practices, procedures, and search tools. They are encouraged to attend seminars, webinars, workshops, conferences, and courses in their technical fields, including S&E practices. During periodic team meetings they discuss cases and professional topics.

CPC training

CPC training programs are provided to the ILPO examiners, including frontal and distance learning courses conducted by the ILPO and other Offices.

o Professional courses

Several advanced professional courses have been held at the ILPO, provided by leading Israeli universities and private firms. The courses focus on emerging technologies and the last developments in different technical fields. In addition, an annual patent law training program is in place, including administrative law, case law, updates to Israeli Patents Law and Regulations, comparative law, and legal search database training.

Training the trainers

Senior patent examiners take mentoring courses on teaching, evaluating, and giving feedback for new examiners.

Training resources for the administrative staff - PCT formalities examiners

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

PCT formalities examiners are authorized to make their own decisions after thorough verification of their competencies and skills. The PCT Department holds periodic team meetings for discussing all the issues raised in the processing of international applications at all stages.

Research projects for candidates to senior examiners

Patent examiners are required to conduct research projects on selected topics related to the prosecution of patent applications, as a prerequisite for promotion to senior examiners. The projects offer comprehensive analysis, conclusions and recommendations for improvement.

Study visits to the industry and academic institutions

The ILPO organizes visits for examiners to industrial firms and academic institutions in Israel. These visits include tours, lectures, and discussions on scientific, technological, and IP-related aspects in various advanced technical fields.

Offshore training

ILPO examiners participate in offshore training programs through examiner exchange arrangements with other offices, study visits, and information exchange meetings. These programs offer training in examining, classifying, and processing patent applications.

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 4 below.

4. MANAGEMENT OF ADMINISTRATIVE WORKLOAD

21.16 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

The Team Managers take charge of performing quality checks for the substantive examination, managing workload, providing professional support to examiners in search and examination as well as performing other managerial tasks.

The PCT Department has experienced staff who conduct administrative tasks, as detailed above, including processing applications, handling Demands for Preliminary Examination (IPEA), mailing notices and reports, and monitoring the timeliness of PCT S&E reports.

The automated system (PCT-SAPIA) assists in timely issuance of international reports and communications during the RO and ISA/IPEA stages, providing a quality assurance mechanism (see Section 5 below).

The Patents and PCT Departments use a Business Intelligence (BI) system to monitor workflow and track processing timeliness and backlogs. The BI system offers customizable parameters and comprehensive work analytics and statistics.

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

Management uses the BI system for continuously monitoring both fluctuations in demand and possible backlogs to ensure there are enough resources available at all times.

A management model is implemented for dealing with unexpectedly high demand. The model covers a range of coordinated actions including efficient work distribution and information exchange, and readiness for providing immediate training upon need.

A bot-based deep mapping system automates patent application mapping by considering examiner skills, application complexity, and data from PCT reports, leading to more efficient allocation of applications.

An incentive program for the examiners is in place to improve the examination quality and efficiency, and to maintain compliance with the service level agreement.

5. QUALITY ASSURANCE

21.17 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.

Management utilizes a business intelligence (BI) system as a strategic tool for analyzing and enhancing performance and quality metrics. Additionally, it serves as a monitoring mechanism to track the effectiveness of preventive and corrective actions implemented.

The Quality Manager reports directly to the Director of the ILPO on matters regarding quality of services, based on available feedback from the Directors of Departments, the Quality Control Officer, Team Managers, examiners and customers.

Examination Guidelines are periodically updated to address certain needs such as enhancing examination standards, improving user services or accommodating changes in legislation and practice. This mechanism involves Management, Quality Manager, Quality Control Officer and Examination Guidelines Team (please see also paragraph 21.06(b) above).

The Team Managers in the Patents Department are responsible for the quality control of the national Office Actions and the international reports produced. They conduct semiannual evaluations for the examiners and oversee their professional development.

The Quality Control Officer takes charge of the quality checking of the substantive examination of national patent applications, updating the Examination Guidelines and the national Standardized Clauses, managing the BI system, and providing productivity and quality reports to each examiner and to Management.

The Knowledge Management Officer takes charge of identifying, extracting, preserving knowledge assets, and making them available for all patent examiners.

Directors of the Patents Department are responsible for managing resources, guiding teams, and ensuring uniform practices among the different teams. The objective is to maintain consistency in the search and examination of all patent applications, regardless of which team handles them.

Standardized Clauses, prepared by the International Authorities, are available to the examiners for use in the ISA and IPEA reports.

The reports on characteristics of ISRs prepared by the International Bureau are analyzed and discussed by the Board of the ISA/IPEA and by the management of the Patents Department. This analysis aids in the self-assessment regarding the search and examination work.

As part of the internal quality assurance system for self-assessment and improving the quality of search and examination, a comparative analysis mechanism is applied to check the prior-art documents cited by Designated Offices with respect to those cited in the IL ISRs. In addition, a

pilot program has been established to compare search results from ISAs other than the ILPO with those established by the ILPO for corresponding accelerated applications first filed in Israel.

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. In addition to using checklists and monitoring timeliness, the PCT Department also analyzes monthly the invitations received from the IB. The Director updates staff on new PCT Circulars and changes in Regulations and Guidelines. The PCT Department has prepared standardized clauses for use in formalities examination during the RO, ISA, and IPEA stages, as well as upon entry into the National Phase.

The ILPO has an internal quality assurance system for international reports that evaluates administrative and search & examination work for compliance with PCT/AI, PCT/GL/RO, and PCT/GL/ISPE. This system includes the following checking procedures:

- Automatic quality checking by the automated system PCT-SAPIA PCT-SAPIA performs comprehensive automated validations and provides guidance and warnings to prevent errors and ensure integrity of the reports issued. The guided examination and quality control mechanisms integrated into the system obviate the need for checklists. PCT-SAPIA provides a task list for formalities and substantive examiners, quality control reviewers, and the payment coordinator, with reminders to alert of upcoming deadlines. Tasks are color-coded for easy identification of time limits. A daily query is run to identify applications requiring attention to take the appropriate action in due course.
- Checking by a quality control reviewer and by a second examiner
 - At the RO stage, at least 5% of the applications are cross-checked by a second examiner.
 - At the ISA and IPEA stages, three kinds of checking are performed:
 - Substantive examination checking: The Team Managers, acting as quality control reviewers, check 100% of the international reports. In cases of all-[A] ISRs, a second examiner may perform a new search before issuing the ISR. The quality control checking of the international reports is indicated in PCT-SAPIA.
 - ISA/IPEA formalities examination check: The ISA/IPEA formalities examiner reviews all PCT forms (including search strategies) to ensure detail integrity and consistency before sending them to the applicant and IB.
 - Periodic audit of a random sample of cases: 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 documented in the automated system.

6. COMMUNICATION

Inter-Authority communication:

21.18 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 21.18)

21.19 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 people:

Mr. Imad Zakharia, Ph.D., Senior Patent Examiner & Coordinator of PCT QSG at the ILPO ImadZ@justice.gov.il

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

Israel Patent office Malcha Technology Park, Eshel Building (number 5), 1 Agudat Sport Hapoel St. Jerusalem 9695102 Israel

Communication and guidance to users:

21.20 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.

To enhance the quality of PCT applications, the ILPO has implemented various mechanisms for receiving feedback from applicants at all stages of processing international applications:

Communications between applicant/agent and examiner

In invitations, notifications and reports, the name of the examiner is provided as well as the telephone number and email address. Formalities examiners are advised to communicate with the applicant via email or telephone to promptly resolve any ambiguities that may arise.

User feedback

The ILPO uses several methods to collect user's feedback:

- Online External Quality Survey System: The ILPO collects annual feedback through an external Online External Quality Survey System, in which users rate receiving, processing and examination services and optionally leave comments and suggestions anonymously.
- Internal Quality Survey System: An internal electronic survey is annually conducted for all ILPO departments and satisfaction feedback is collected from the ILPO staff 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.
- <u>Roundtables</u>: The PCT and Patents Departments hold roundtables with patent agents, industries, universities, and private applicants to understand their needs, update them on developments and new ILPO services, and gather suggestions and complaints.
- <u>User Feedback on legal changes</u>: The ILPO posts updates to the Commissioner Circulars and Examination Guidelines on its website for feedback before they become effective. This feedback is considered when finalizing the documents.
- Study visits to the industry and academic institutions: The examiners visit industrial firms and academic institutions in Israel to discuss scientific, technological, and intellectual property matters. These discussions help gather feedback on ILPO services.
- Other methods: Further feedback can be received via phone, email, or in-person meetings. Help Desks for the Patents and PCT Departments handle customer complaints and assist with various patent issues. The ILPO's Quality Manager reviews feedback data, reports to top management, and recommends improvements. Customer feedback results are considered for future updates to ILPO guidelines, training, and quality policy.

Guidance and information for users

The ILPO's website offers information, guidance, and updates in Hebrew, English, and Arabic, including details on national and international applications as well as the Examination Guidelines. Users can also subscribe to the ILPO mailing list for direct news updates. A link to the WIPO website regarding PCT prosecution is provided for international applications. The e-filing systems use automated customer behavior analytics to understand and improve user experience in real time (see paragraph 21.15(iii-iv) – E-filing systems).

The ILPO assists applicants with filing and e-filing national and international applications, and provides guidance and information through face-to-face communication, telephone and email support, seminars and webinars, roundtables upon request, and comprehensive information available on the ILPO's website.

Agents are invited to attend meetings about the PCT process, e-filing, e-payment, and the roles of RO, ISA, IPEA, and the national phase. These meetings address issues and potential improvements in the PCT system.

ILPO advises users to file a national patent application requesting accelerated examination and a subsequent PCT application claiming priority from the national application. This approach provides early search results for making necessary changes before filing the PCT application and allows refund of 50% of the PCT search based on use of search results.

21.21 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.

The PCT Department manages paperless communication with WIPO and designated/elected offices, addressing their feedback to management. Communications with WIPO are mainly conducted via PCT-EDI system, e-mail, and telephone. The PCT Department Director receives WIPO Circulars and significant changes, of which he ensures that the staff is informed, and any procedural modifications are implemented. In addition, he regularly attends WIPO meetings.

7. DOCUMENTATION

21.22 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 21.23).

(Note: This point is informative. No response is required by the template to paragraph 21.22)

21.23 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 Quality Manual and Work Instructions, including Examination Guidelines, are available on each ILPO department's intranet homepages. The Examination Guidelines are also on ILPO's website in Hebrew and English. Updated Work Instructions with new version numbers are distributed to the relevant staff and published on the intranet. Previous versions are kept for reference. For more details, see section 3, paragraph 21.15(v) Documentation of instructions.

- 21.24 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 QMS.

All ILPO employees are committed to following quality procedures. Every department uses control procedures to ensure compliance with the Quality Manual and Work Instructions.

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

21.25 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 8.

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

8. SEARCH PROCESS DOCUMENTATION

21.26 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 PCT-SAPIA system maintains documentation for each application's search process. As it generates international reports for Chapters I and II, all relevant data is stored within this system. This includes databases consulted, search strategy, IPC and CPC classifications, minimum documentation searched, search limitations and justifications, claim clarity issues, and lack of unity. The system also records examiners' notes and communications.

Classification of subject matter according to the CPC is included in the international reports established by the ILPO in addition to the IPC. The internal system provides an automatic CPC to IPC concordance, enabling the examiners to classify the subject matter mainly according to the CPC.

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

9. INTERNAL REVIEW

21.27 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.

21.28-21.30 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 twice a year. These reviews are presented to top management at management reviews. Please see 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 with 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.

10. ARRANGEMENTS FOR AUTHORITIES TO REPORT TO THE MIA

21.31 There are two stages in the reporting arrangements outlined in Chapter 21: the initial report called for by paragraph 21.31(a), and annual reports in accordance with paragraph 21.31(b). 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.

[End of document]