

REPORT ON THE QUALITY MANAGEMENT SYSTEM

prepared by the State Enterprise "Ukrainian Intellectual Property Institute"

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.

Abbreviations used in the document

Ministry	– Ministry of Economic Development and Trade of Ukraine
Ukrpatent	– State Enterprise "Ukrainian Intellectual Property Institute"

INTRODUCTION (CHAPTERS 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

According to the Resolution of the Cabinet of Ministers of Ukraine of 11.05.2017 No 320 the State Intellectual Property Service of Ukraine ceased to perform its functions to implement the state policy in the intellectual property sphere. Activities related to their performance have now been taken over by the Ministry of Economic Development and Trade of Ukraine.

According to the Agreement (signed in Geneva on October 5, 2017) between the Ministry of Economic Development and Trade (the Ministry) and the International Bureau of the World Intellectual Property Organization (WIPO) the functions of an International Searching Authority (ISA) and International Preliminary Examining Authority (IPEA) are performed by the examining authority – the State Enterprise "Ukrainian Intellectual Property Institute" (Ukrpatent). The Agreement on performing of the ISA/IPEA functions by Ukrpatent signed in Geneva remains in force up until December 31, 2027.

A quality management system (QMS) in conformity with the ISO 9001:2015 standard requirements has been implemented and used at Ukrpatent.



In July 2018, an independent certification organization performed the audit (compliance audit) of the QMS compliance with the ISO 9001:2015 standard requirements at Ukrpatent. The audit results demonstrated that the QMS corresponds with the ISO 9001:2015 standard requirements.

No significant changes were observed in the functioning of the QMS at Ukrpatent in 2018.

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 organizational chart showing all those bodies and individuals responsible for the QMS.*

(a) The quality policy established by the top management

The Conception of Development of the State System of Intellectual Property Legal Protection for 2016-2018, defines one of the priority tasks as quality improvement of examination of applications for intellectual property rights, strengthening of intellectual property rights protection with consideration of internationally recognized approaches by means of:

- implementation of electronic proceedings of examination of applications for intellectual property rights;
- improvement of the technology of applications for intellectual property rights consideration on the basis of automated systems implementation;
- enhancement of the methodological support of the processes of examination of applications for intellectual property rights, provision of identical application of legislative norms, and precedent formalization;
- implementation of the system of application filing through the Internet in electronic form and minimizing the volume of applications filed on paper carriers;
- keeping the pendency time of applications for intellectual property rights on the level provided by the applicable convention priorities under the Paris Convention for the Protection of Industrial Property;
- improvement of applications examination quality control.

Conformity with the international ISO 9001:2015 standard is provided at Ukrpatent. There the Quality Coordination Board is functioning, a quality management representative has been appointed, individuals responsible for the QMS implementation and maintenance in structural divisions have been appointed, the necessary documented procedures have been determined and developed.

The quality policy is determined and presented in the Quality Manual endorsed by the order № 107-H/2018 from 25.06.2018.

(b) The roles and names of those bodies and individuals responsible for the QMS; as delegated by the top management

To coordinate the works on development, implementation and maintenance of the functioning of the QMS processes, to prepare and submit to the top management summarized information concerning the QMS functioning, effectiveness and needs of its improvement, Petro Ivanenko, the Director for Innovation and Information Development, has been appointed as the quality management representative.

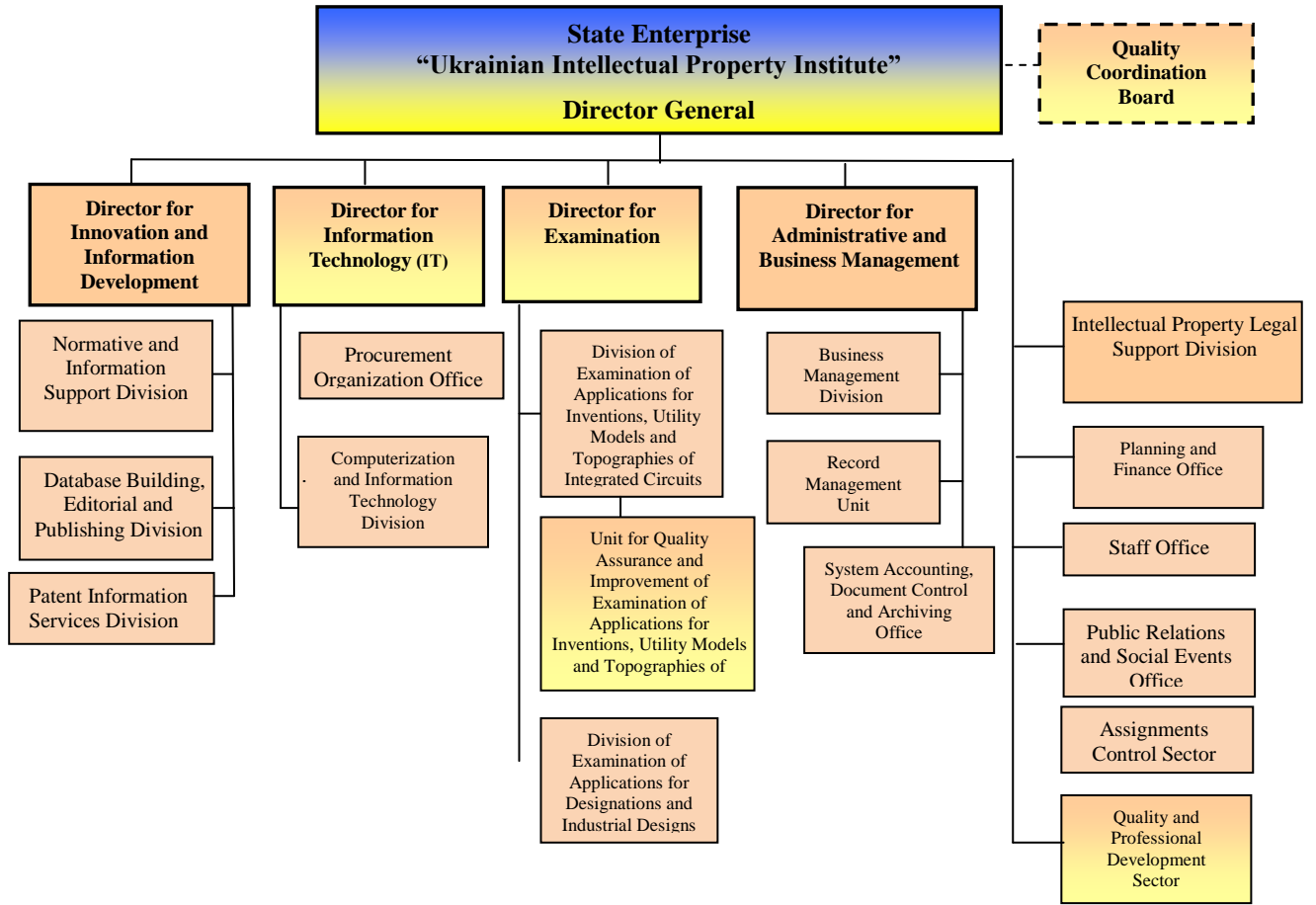
The Quality Coordination Board is a standing consultative collegial body under the Ukrpatent management.

The main tasks of the Quality Coordination Board are: policy making and goal setting in the quality sphere; determination of the QMS principles, processes and model conforming to the requirements set out in ISO 9001:2015 and Part VII of the PCT International Search and Preliminary Examination Guidelines and satisfying customers' needs; the QMS control and management, its analysis and improvement.

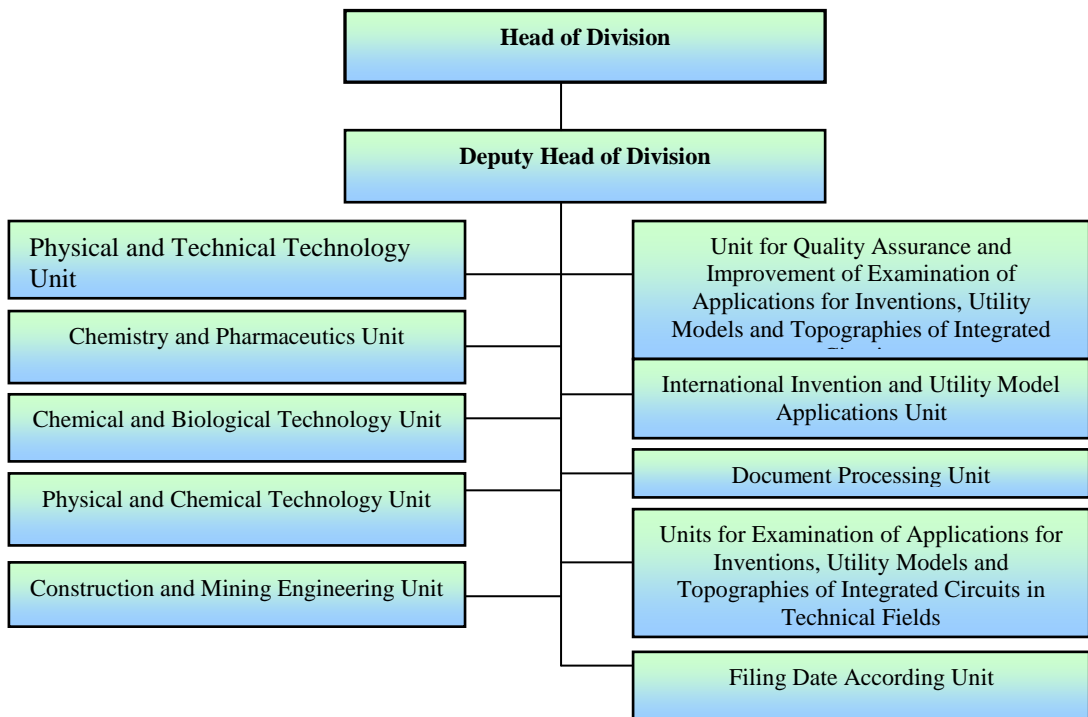
The Quality Coordination Board meets at least once every six months. In 2018 2 (two) meetings of the Quality Coordination Board were held.

The QMS organizational structure is presented below.

(c) An organizational chart showing all those bodies and individuals responsible for the QMS



Structure of the Division of Examination of Applications for Inventions, Utility Models and Topographies of Integrated Circuits



21.05 Indicate (e.g. by means of a table) the extent of compatibility between the Authority's QMS and the requirements of Chapter 21 of these International Search and Preliminary Examination Guidelines.

Alternatively, indicate where the Authority is not yet compliant with these requirements.

[Sample table, to be amended as necessary]

Chapter 21 requirement			Extent of compliance		
			full	part	no
21.04	(a)	Quality policy available	✓		
	(b)	Identified roles and names for QMS responsibility	✓		
	(c)	Organizational chart available	✓		
21.05		Established compatibility of QMS with Chapter 21	✓		
21.06	(a)	Mechanisms to ensure effectiveness of the QMS	✓		
	(b)	Control of the continual improvement process	✓		
21.07	(a)	Communication of management about this standard to staff	✓		
	(b)	The PCT Guidelines are in line with the Authority's QMS	✓		
21.08	(a)	Management reviews take place	✓		
	(b)	Quality objectives are reviewed	✓		
	(c)	Communication of quality objectives throughout 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 based on Chapter 21	✓		
		determine the extent to which S&E complies with PCT Guidelines	✓		
	(c)	an objective and transparent way	✓		
	(d)	using input incl. information according paragraph 21.24	✓		
(e)	recording the results	✓			
21.10		Assurance to monitor and adapt to actual workload	✓		
	(i)	Infrastructure in place to ensure that a quantity of staff	✓		
	(a)	sufficient to deal with the inflow of work	✓		
	(b)	which maintains tech. qualifications to S&E in all technical fields	✓		
	(c)	which maintains the language facilities to understand languages according to Rule 34	✓		
	(ii)	Infrastructure to provide a quantity of skilled administrative staff	✓		
	(a)	at a level to support the technically qualified staff	✓		
	(b)	for the documentation records	✓		
	(iii)	Ensuring appropriate equipment to carry out S&E	✓		
	(iv)	Ensuring documentation accord. to Rule 34	✓		
	(v) (a)	Instructions to help staff understand and act accord the quality criteria and standards	✓		

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

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

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

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

(a) the effectiveness of the QMS

The quality policy making and implementation are the responsibilities of the management of Ukrpatent and the quality management representative.

In order to assess the QMS efficiency, Ukrpatent management yearly develops and formulates benchmarks and indicates the divisions and/or division heads responsible for ensuring their achievement, and approves the QMS internal auditing program.

The results of the internal audits are discussed and analyzed at the Quality Coordination Board meeting, and summarized conclusions are submitted for consideration to the Director General of Ukrpatent in order for respective decisions aimed at the quality activities improvement to be taken.

(b) that the process of continual improvement progresses

The quality management representative carries out general management and coordination of the activities of the individuals responsible for the QMS implementation and maintenance in structural divisions, as well as of the QMS implementation and audit sector in the matters of the QMS efficient development, implementation and improvement.

The most crucial issues and prepared propositions are discussed at the Quality Coordination Board meetings and management talk-ins; the decisions made during such meetings and talk-ins are recorded in protocols, orders and directions.

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.*

Ukrpatent communicates to the staff the importance of fulfillment of the QMS requirements, including requirements under the PCT, relating to the international search and international preliminary examination quality provision, through orders and directives of the management, weekly operational meetings with the Director General of Ukrpatent, training seminars, Quality Coordination Board reports and protocols, Ukrpatent Annual Report; the information about these events and documents is promptly distributed by e-mail and through the internal information network (Intranet Portal).

Beside this, the top management brings the requirements of the quality management-related standards and regulatory documents to the examiners' attention through the specially created Reference and Information Section in the "Inventions" automated system (AS) accessible to all examiners from their own workstations.

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) Conducts management reviews and ensures the availability of appropriate resources

Ukrpatent top management develops and forms benchmarks directed toward quality improvement based on the Quality Policy.

The QMS analysis and goal achievement level are performed twice a year at Quality Coordination Council proceedings.

The QMS functioning report is a summary document from the management, based on which the management works out the QMS development plans, elaborates the QMS modification and/or improvement decisions, and assigns resources required for the QMS functioning.

The QMS analysis was carried out in the course of the Quality Coordination Board meeting on June 22, 2018. The goals and tasks in the quality sphere were defined at the Quality Coordination Board meeting on February 8, 2018.

(b) Reviews quality objectives

The top management reviews are carried out by the Quality and Professional Development Sector under the orders of the Director General of Ukrpatent according to the QMS auditing program.

Should the need arise unscheduled reviews on separate matters can be carried out. In 2018, 1 (one) QMS internal audit was carried out within divisions. The internal audits results analysis was conducted at the Quality Coordination Board meeting in June 2018. The QMS tasks are reviewed in the course of planning Ukrpatent activities for the following year. The QMS external audit was carried out in June 2018.

(c) Ensures that the quality objectives are communicated and understood throughout the respective Authority

The personnel is able to promptly access necessary documents and view the results of the QMS functioning through the orders or directives sent to the structural divisions and published on the Ukrpatent Intranet Portal, as well as in the course of staff meetings in the divisions.

Beside this, information on the results of examination quality checks, new operation procedures and other information concerning Ukrpatent activities are sent to the heads of examination divisions to be forwarded to the divisions' staff and for further reference.

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

(a) at least once per year (cf. paragraph 21.22);

(b) in accordance with the minimum scope of such reviews as set out in Section 8, namely:

to determine the extent to which the QMS is based on Chapter 21 (cf. paragraphs 21.22, 21.24(i));

to determine the extent to which Search and Examination work complies with PCT Guidelines (cf. paragraphs 21.22, 21.24(i));

(c) in an objective and transparent way (cf. paragraph 21.22);

(d) using input including information according to paragraphs 21.24 (ii)-(vi);

(e) recording the results (cf. paragraph 21.25).

See 21.05, 21.08.

Each month, meetings with the participation of the Director for Examination, the Director for Information Technology, the Head of the Examination Division as well as individuals responsible for quality control are held.

The meetings are dedicated to discussing current quality management issues, availability of necessary resources and measures to be taken to satisfy immediate needs.

Results of such meetings are brought to the attention of respective examination units or individual examiners for further reference.

Beside this, internal automated routine and randomized examination quality control is provided at Ukrpatent.

Routine quality control is carried out by tutor examiners and heads of examination units in separate industrial fields.

Randomized control is carried out by the Head/Deputy Head of the Examination Division and by the Head of the Quality Control Unit.

All decisions about non-compliance of an invention with the patentability conditions are subject to 100% check by heads of examination units in the industrial fields, the Quality Control Unit and the Head/Deputy Head of the Examination Division.

In 2016 the system of internal organizational and administrative documents regulating monitoring and assessment of the quality of work of examiners of the Examination Division was amended, in particular, the Classifier of Errors in the works on examination and processing of applications for inventions, utility models and topographies of integrated circuits and the Classifier of Quality of the works on examination and processing of applications for inventions, utility models and topographies of integrated circuits were developed.

The Classifier of Errors is intended for the officials who carry out internal quality control of individual works to classify and code (index) the revealed violations by their nature.

Coding (indexing) of the revealed violations in accordance with the Classifier of Errors is aimed at ensuring accumulation of statistical data in the "Inventions" AS suitable for the automated statistical analysis of the results of internal quality control for application of its results in planning and implementation of measures for training

and retraining of employees of the Division aimed at improving the quality of work of the employees and the Division's units.

The Classifier of Quality is intended for assessment of the quality level of the checked work and coding (indexing) of the assessment outcome by the officials who carry out internal quality control of individual works in the Division. The quality level of the given work relating to the specific application is determined by the expert method.

Coding (indexing) of the quality assessment outcome is aimed at providing automated statistic analysis of the results of the internal quality control for application of its results in planning and implementation of measures for training and retraining of the employees of the Division aimed at improving the quality of work of the employees and the units of the Division and to use its results in organization of the selection, placement, material and moral incentives of the personnel of the Division.

When carrying out searches, examiners must:

- provide for the use of the PCT minimum documentation;
- check the observance of the invention unity principle;
- correct the initial classification;
- determine relevant categories in search reports;
- bring forward clear arguments in case an invention does not comply with the novelty and inventive step conditions.

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 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;

for the documentation of records.

(i) Provide information about the infrastructure in place to ensure that a quantity of staff:

The total number of examiners performing the examination of inventions is **115** persons.

All of them are employed full time and have a higher education (specialist's/master's degree) in respective field and a second university degree in the intellectual property sphere; among them there are also 6 PhD degree holders. Experience and knowledge of the Ukrpatent examiners allow for high-level search and examination in the following fields: nanotechnology, pharmaceuticals, chemistry, biotechnology, agriculture, metallurgy, electronics, telecommunications, etc.

All examiners are fluent in Ukrainian, Russian and English. Some of the examiners also have sufficient knowledge of German, French, Spanish, Polish and Japanese.

On a regularly basis at the monthly management meetings with participation of the Director for Examination, the Director for Information Technology, the Head of the Examination Division, the Head of the Staff Office as well as individuals responsible for quality control the necessity in resources, including human resources, according to the present workload (application filings) is assessed.

At these meetings, decisions about new examiners recruitment are made, qualifying requirements to them with the consideration of the needs for high quality examination performance are determined, educational and/or professional development activities schedules are approved.

Newly recruited examiners are assigned tutors from among the experienced senior examiners having the signing authority. Such tutors organize trainings and check the work performed by junior examiners.

The training of examiners is organized on an ongoing basis in the form of trainings dedicated to performing and documenting searches and case studies.

Beside this, examiners are able to improve their qualification within the international cooperation framework and taking part in the events organized in Ukraine.

(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;

To provide the high quality examination, each examiner has been provided access from their own workplace to document processing regulations, materials on examination methodology, instructions, directives and interpretations provided both by the legal team and given on the division level based on the results of respective

training by placing them in the reference and information section of the “Inventions” AS.

Access to legislative documents of Ukraine, WIPO standards, Paris Convention for the Protection of Intellectual Property, Patent Cooperation Treaty (PCT), Regulations under the PCT, PCT Administrative Instructions, Patent Law Treaty (PLT), Regulations under the PLT, PCT International Search and Preliminary Examination Guidelines etc. is provided in the same way.

Within the international cooperation framework examiners take part in the following events:

1. WIPO Academy Distance Learning Program (on an ongoing basis).

DL-101 (general course) certificates were received by almost all examiners.

Those examiners who have received DL-101 certificates take part in further learning programs DL-320, DL-318, DI-301, DL-202, DL-204 (advanced level).

2. On-line training on the matters of examination and patent information searches organized by the European Patent Office (EPO), business trips on training and other matters connected with optimization of the use of EPOQUE Net retrieval system (regularly).

3. Training events regularly organized by the EPO on the matters of quality control in patent searches and examination and other examination and patent search-related matters.

4. Participation in the meetings of the Working Groups of the International Patent Classification (IPC) Union Committee of Experts.

5. Study visits and/or seminars organized by the WIPO to promote sharing experience and networking of representatives of the PCT receiving offices on the matters of international applications proceeding, processing of international applications filed in the electronic form using the WIPO PCT-SAFE software and the use of electronic services (ePCT and/or PCT-ROAD systems in particular).

Events organized in Ukraine:

The round-table meeting on current intellectual property issues was held in Ukrpatent on 26 January 2018 with the participation of the WIPO Deputy Director General responsible for the Patents and Technology Sector Mr. John Sandage, and with the participation of domestic patent attorneys and the representatives of the business community.

The WIPO National Patent Drafting Workshop was held in Kyiv (Ukrpatent) on 4-8 June 2018. The coordinators: the Ministry and Ukrpatent jointly with WIPO.

The conference "Actual Issues of Acquiring Rights to Industrial Property, Their Protection and Commercialization" was held in Ukrpatent on 14-15 November 2018.

Training of examiners on the matters of examination and use of databases (STN, REAXYS, EPOQUE Net, DWPI etc.) conducted in particular by the providers of the mentioned databases.

Seminars and conferences organized by the National Academy of Sciences and branch Academies of Sciences of Ukraine as well as enterprises and educational institutions. Regional seminars organized with the aim of raising awareness of the Ukrainian public on the PCT system

for the documentation of records.

Computerization and Information Technology Division provides additional support to technically qualified employees by supplying them with the necessary software and equipment.

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 when necessary.

For information support, all up-to-date methods, forms and means are utilized: the Internet (the SIPS web-portal, the Ukrpatent web-site, Intranet Portal, the Digital Patent Library web-site, foreign commercial information resources, national and foreign information resources available free of charge), official and specialized publications, printed and electronic mass media, international cooperation in the sphere of patent information and documentation. Specific functions concerning constituent elements of the set of works on information support are entrusted to the respective structural divisions of Ukrpatent, in particular Normative and Information Support Division and Computerization and Information Technology Division.

(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

Information and technical support is ensured by Computerization and Information Technology Division, System Analysis and Information Technology Development Office and Key Certification Centre. These units perform the following functions:

- Information Technologies Implementation and Maintenance Office provides for software development, implementation, maintenance and operation as well as database administration;
- Automated Systems Operation Office provides hardware servicing;

- System Integration and Communication Technology Office ensures the work of communication systems and server equipment and automated system operation security using antivirus software and maintaining operating systems in a proper condition by regularly updating them, as well as provides user access to the resources of the local computer network.
- Information Technology System Analysis and Development Office provides for development of technical specifications for creating new automated systems, carries out implementation and administration of the system of electronic filing of applications for industrial property rights, administration of the Digital Patent Library and Internet databases administration;
- Key Certification Centre carries out registration and servicing of the subscribers of the accredited Key Certification Centre, provides for generation of personal keys and electronic digital signature (EDS) certificates; provides for the consultations to registered subscribers and respective structural divisions of Ukrpatent on the matters of EDS use and work with EDS means; provides for the guidance to users of electronic application filing system.

All examiners have at their disposal up-to-date personal computers connected to the internal computer network and Internet and have authorized access to the special applied software to fulfill the functions of application examination.

The core of the prosecution of applications for inventions is the “Inventions” automated system (AS) which ensures the feeding of data and forming “electronic application files”, the full cycle of the document workflow of examination of both national and PCT applications (national phase), maintaining the state registry and archive, forming statistical reports and information arrays to be published on the Internet.

To ensure data exchange, a bilateral connection between Ukrpatent and the International Bureau of WIPO has been established through the PCT-EDI system. This channel is used by the International Applications Unit which provides for the fulfillment of the functions of a Receiving Office for documents exchange (international phase). Notifications on applications status are generated automatically and forwarded to the International Bureau each month.

Also, access to the ePCT system has been established; the system is intended to provide safe on-line access to the documents of international applications, their viewing and downloading.

Ukrpatent receives documentation both on paper carriers and in electronic form.

All documents received on paper are scanned to produce colour image, and recognized. As a result, a file in PDF/A format is sent to the database. The text of the document is indexed to further enable full-text searches. Documents are stored in technological databases managed by the Microsoft SQL Server 2008 database management system (DMS).

At Ukrpatent a system of electronic document filing with the use of electronic digital signature is deployed. Documents in electronic form are also forwarded through a

special buffer to the same technological databases and stored there in the original form together with the electronic digital signature. These electronic documents are converted into PDF/A format and stored in the technological databases alongside with the original files.

Prosecution of intellectual property rights (IPR) applications and other processes, related to the activities of Ukrpatent, are maintained by means of the software and hardware complex (SHC) arranged in the computer network of Ukrpatent. The SHC is an integrated information system incorporating technological automated systems, databases, e-document flow, e-document archive, systems for document recording, accounting and generating data arrays to be published.

Automated systems are based on the client-server architecture. There are SHC fail-safe operation, server and data storage virtualization technologies implemented.

Equipment stock comprises of about 650 personal workstations, 25 physical and data storage systems utilizing disc arrays with the total storage capacity over 200 TB.

Physical layer of the IT infrastructure incorporates the structured cabling system (SCS), the data processing center (DPC) and the automated workstations. The SCS was installed and certified as a part of construction of the Ukrpatent building in 2004. The DPC includes the following:

- server hardware and data storages providing for the DPC core functionality, i.e. data processing storing;
- network and telecommunication infrastructure providing for the interconnection of the DPC components, as well as for the data transmission between the DPC and clients;
- engineering infrastructure providing for the operation of the core DPC systems by way of:
 - indoor temperature and humidity level maintenance within the set parameters;
 - uninterrupted power supply for autonomous operation in case of isolation of the central power supply sources;
 - security and fire alarms, and gaseous fire suppression systems;
 - access control.

Automated workstations used by the examiners incorporate personal computers, printers, image scanners and other peripheral devices. Users of the information processing systems are provided with Internet connection to be able to search and retrieve information.

The common network infrastructure consists of the Check point 5600NGTP Security Gateway incorporating VPN and Firewall modules to provide for the safe Internet connection and internal router (Unix-based) to support the local area network, and also of Barracuda Spam & Virus FireWall for spam protection of mail servers. The presence of two network screens increases overall security.

The network switches use HP and Cisco equipment.

The internal network is divided into 15 virtual networks (VLAN).

The following technical means are used in the network:

- HP servers (DL380Gen8, DL380G7, DL380G5, DL360 Gen8, DL360 G5, DL320 Gen8);
- Data Storage Area HP (3Par StoreServ 7200, MSA2040, P2000, MSA2324fc, MSA1000), Infortrend (EonStor S12F-R1420, EonStor S16F-R1430);
- SAN network equipment (HP SN3000B, HP SAN Switch 8/24, Qlogic SANbox 5600);
- HP local network equipment (ProCurve Switch 2910al-24G, ProCurve Switch 2510-48, 2530-48 Switch).

Operating systems and software:

- the servers are operated via operating systems Windows Server 2016, Windows Server 2012R2, Windows Server 2012, Windows Server 2008R2, Windows Server 2008, CentOS 7;
- virtualization servers are based on Microsoft Hyper-V Server 2012R2 ta VMware ESXi;
- the databases are administered via MS SQL 2016, MS SQL 2014, MS SQL 2008R2, MS SQL 2005.

There is a domain Active Directory (AD) system established enabling centralized control of all information resources including users, computers, files, peripherals, service access, network resources, websites, databases, etc.

To ensure fail-safe operation of the domain structure, a few domain controllers are used.

WSUS server provides for the update of the operating systems of the servers and the client PCs.

ESET Endpoint Antivirus server provides for the master control of the antivirus software installed on all client PCs, update of the virus definitions, the report preparation on the virus definitions update and the current hazards.

Data backup is provided for via the Microsoft software product – System Center Data Protection Manager (DPM) which enables continuous data protection aimed at secure restoring the operation of the Windows servers. There is a plan for restoring operation of all servers and services after the crash.

The IT infrastructure development activities that were carried out during the current period were aimed at building a high availability core of computer network, increasing the network capacity, security and controllability, replacing obsolete components of the hardware part of the infrastructure, consolidating and virtualizing

servers. Virtualization servers are joined in clusters enabling high availability of all systems.

A number of arrangements have been introduced to ensure that IT infrastructure meets the requirements of an integrated information security system. The ports of the network switches have Security feature turned on, which makes it impossible to connect a third-party device to the corporate network. Changes in password policies that meet security requirements have been made.

The ports of the network switches have the Port Security function which makes it impossible to connect a third-party device to the corporate network. The changes in Password Policies that meet security requirements have been made. A system of two-factor authentication of users is implemented on the basis of hardware-software generating device and electronic digital signature checking system. The protected HTTPS protocol and SSH application layer network protocol are implemented for managing network equipment, storage and SAN switches.

The connection to Internet intended for browsing is implemented for the users of information systems.

The search and retrieval subsystem incorporates means for the full-text search, presentation and further processing of the search results. The search is carried out based on the search criteria in "Inventions" AS, which contains information on the filed applications and registered patents for inventions and utility models in Ukraine. The search queries can be either simple of one search criterion, or complex involving Boolean operators (AND, OR, NOT), brackets, inter-word distance operators, combination and delimiter statements. The search criteria are entered via the graphical interface or via the expert mode (text-based query).

The Search Portal is an integrated solution combining patent and information resources of Ukrpatent and foreign IP offices. It is aimed at facilitating patent searches within the substantive examination of applications for inventions. Various data sources in the Search Portals are integrated in a single shared storage by uploading and indexing of the core search arrays of the national and foreign patent documents. To facilitate the use and to increase the search rate, databases, contained on the optical media, are converted into electronic databases as part of the active data storage, linked to the Search Portal.

The Search Portal enables automation of the following business processes:

- substantive examination of applications for inventions (full-text search across patent documents collections of the foreign IP offices);
- data import from external sources of patent documents;
- data import from an external non-patent literature source (library information and reference collection);
- full-text search in the non-patent literature database;

- recognition of scanned documents and storing of the retrieved texts in the non-patent literature database within the Search Portal.

The patent documents collection within the Search Portal is updated by means of specific software system enabling retrieval of the patent data in XML from FTP servers of the foreign IP offices and uploading thereof to the current data warehouse.

(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.

Electronic information resources available at Ukrpatent cover patent documents from organizations and patent offices of the countries forming the PCT Minimum Documentation.

For over 20 years, acquisition of patent documents collections of foreign countries for the abovementioned resources has been carried out mainly through the cooperation with WIPO, exchange with the European Patent Office (EPO), the Eurasian Patent Office (EAPO) and the national offices. In 2003, under the Law of Ukraine "On the Protection of Rights to Inventions and Utility Models" Ukrpatent as an examining authority was declared to be the center of international exchange of publications that provides the legislative environment for the specified field of activity.

Over the course of 2018 the foreign patent documentation was continuously received within the international exchange on optical carriers which was used for replenishment of the electronic information resources of Ukrpatent (the Search Portal).

In view of the trend to cease publishing of patent documents on material carriers by some foreign offices, Ukrpatent moved to the data exchange via FTP-servers with the following offices: with Rospatent – since 2014, with the JPO – since 2015, with the EAPO – since the second half of 2016, with the Intellectual Property Office of Great Britain – since June 2017, with Austrian Patent Office – since September 2017. This ensures the replenishment of the Search Portal with the patent documentation from the mentioned countries.

National patent documents in the patent information collection are provided for in the form of the Official Bulletin "Promyslova Vlasnist" (Industrial Property) on paper (published since 1993 until now) and on CD-ROM/DVD (published since 2005 until now), specifications to patents of Ukraine for inventions on paper (published since 1993 through 2011), which are also published on CD-ROM "Inventions in Ukraine" (published since 2005 until present). National patent documents are also represented in the "Inventions" AS".

Access to PCT minimum documentation is provided primarily through foreign commercial information resources, which allows increasing the search quality considerably. However, most high-quality free-of-charge national and foreign Internet-resources are used along with the mentioned commercial ones.

Within the last decade opportunities to access the PCT Minimum Documentation (patent documentation and non-patent literature) have considerably increased by means of free and commercial Internet resources, as their number, contents and quality have improved. Thus, using these resources helps to considerably increase the quality of search.

Since 2007, foreign commercial information Internet resources have been used by Ukrpatent which provide access to the PCT Minimum Documentation (patent documents and non-patent literature). For examination purposes 10 foreign commercial information Internet resources were used during 2018, access to which is provided under the appropriate agreements concluded by Ukrpatent:

- the EPO's EPOQUE Net system (**since 2007**);
- STN Files and Features (**since 2008**);
- Science Direct Article Choice (**since 2009**);
- Derwent World Patent Index (**since 2011**);
- REAXYS (**since 2011**);
- Access to Research for Development and Innovation (ARDI) WIPO Program (**since 2012**);
- IEEE *Xplore* Digital Library (**since 2013**);
- American Chemical Society Products (**since 2013**);
- Wiley Online Library (**since 2014**);
- Reaxys Medicinal Chemistry (**since 2018**).

The main search tool among the foreign commercial information resources which are used by examiners to ensure efficient and quality patent search within the substantive examination of applications for inventions and utility models, is the EPO's EPOQUE Net system since it contains patent documents from a large number of countries as required to meet the requirements relating to full accessibility to the PCT Minimum Documentation.

The agreement relating to the granting of access to the EPO's EPOQUE Net is in force since January 1, 2017 till December 31, 2020.

Throughout the term of the agreements for the access to the EPOQUE Net system, Ukrpatent uploads data from the current issues of the national CD-ROM "Inventions in Ukraine" (specifications to patents of Ukraine for inventions and utility models) to the EPO's FTP server.

Provision of the guaranteed access to EPOQUE Net to examiners under agreements with the EPO is also important, as access to the Derwent World Patent Index is granted via this database.

To provide information support for the examination of inventions applications with non-patent literature and PCT Minimum Documentation, public national and foreign Internet resources, in particular, electronic digital libraries and collections (primarily

digital) of **7** largest national-level public libraries of Ukraine, **34** libraries of the specialized scientific institutions of the National Academy of Sciences of Ukraine, **10** libraries of scientific institutions of the Academy of Medical Sciences of Ukraine, **8** libraries of institutions of the Academy of Agricultural Sciences of Ukraine, **19** libraries of the leading higher educational institutions, etc., are also used widely along with commercial resources. Electronic copies of the ordered information sources, in particular, articles in periodicals, are received via the electronic document delivery system.

To increase the level and efficiency of the examination process support by non-patent literature, an active cooperation with the National Library of Belarus was started which became another source of free electronic copies of necessary documents. Currently, in-house electronic information resources, subscribed foreign commercial Internet resources as well as public collections of **89** largest national and specialized libraries (including national electronic digital libraries and electronic collections) used to carry out searches all taken together fully ensure access to the PCT Minimum Documentation.

To support patent searches for determining the compliance of the claimed invention to the patentability conditions, each examiner has access to the Search Portal. The Portal is functionally integrated with the technological automated systems and adapted to the patent information sources (databases), including the national file and foreign patent document collections received on optical carriers.

In order to simplify the use and enhance search efficiency and speed, all patent documents received on optical carriers or via FTP are converted into a single electronic database structure stored in the information warehouse under the PostgreSQL DMS.

To provide access and support searches in the patent databases, a multifunctional search mechanism and information viewers have been realized in the Search Portal. The search mechanism and information viewers allow to:

- perform full-text search in selected sources or a group of sources;
- view search results for each source;
- quickly jump to the text fragment which contains search terms;
- generate reports based on the search results;
- keep the search term history;
- print documents out;
- export documents.

The Search Portal is used by all examiners to perform patent searches.

With the use of the Search Portal examiners can carry out full-text searches using advanced features, for example limitation of intervals between words, search stemming etc.

The Search Portal is designed to be able to forward data to the "Inventions" AS for automatic search report generation.

The System Accounting, Document Control and Archiving Office provides the procedures of system accounting of documents concerning IPR, controls their proceeding in the information and technological process of the IPR application prosecution and provides permanent storage of the IPR application materials and IPR registration files in the archive.

When necessary, the procedure of automated patent search may be supplemented by the traditional search procedure with the use of information on paper carriers available in special archival depositories.

Information documents can be handed to examiners both on paper carriers and in the form of electronic documents distributed via the internal information network.

(v) Control of the QMS documents is a part of the "Control of the Quality Management System Documents" process regulated by the Methodology of Control of the Quality Management System Documents and Workflow Management Regulations and is provided by operation of the respective automated document flow system. The Methodology and Workflow Management Regulations specify: the order of the QMS documents approval; the order of reviewing, updating and re-approving the QMS documents; the ways and means of identifying changes and current revision status of the QMS documents; the order of the QMS documents distribution; requirements as to the documents legibility and identification; the order of identification and distribution management of documents of external origin; actions to prevent unintended use of obsolete documents and the order of application of suitable identification in case such documents are retained for any purpose; requirements as to identification of the QMS documents retention period.

The QMS documentation can be retained and distributed in electronic form via computer network, document workflow automated system or electronic information carriers provided that controlled copies of respective documents on paper carrier and/or in graphic format of PDF are necessarily available. The quality management representative is responsible for control of the QMS documents. Document workflow control and compliance with the documents control requirements are fulfilled by the front office, division heads and employees responsible for the QMS development.

Through the reference and information section of the "Inventions" AS all examiners have access from their workplaces to relevant standards, regulations, instructions, interpretations, regulatory and legal documentation, notices, presentations, prescriptions, information notices sent by WIPO etc. This enables the examiners to maintain high level of awareness, provides the ability to promptly react to changes and improvements of the quality provision system and guarantees the quality of examination and searches.

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.*

The need in personnel training is determined by the division heads on the basis of the personnel's competence level evaluation and with necessary consideration of the requests of the employees wishing to improve their skills. The meeting results are also used for this purpose. The funds necessary for training and skills improvement are allocated according to the yearly planned estimate of expenditures.

Once in three years, a planned employee performance review is undertaken, during which the results of their work, business and professional qualities disclosed in the course of their professional duties fulfillment are estimated. Within the period between the reviews the employees' fulfillment of the tasks and duties imposed on them are assessed. The review and assessment results are documented in the relevant Ukrpatent records and orders retained in the Staff Office.

The training takes the following forms:

- seminars for examiners;
- special workshops on the matters of intellectual property, patent information search and examination of applications for inventions;
- distance learning under the WIPO Academy and the EPO programs;
- discussion forums with representatives and professional organizations in the intellectual property sphere, including applicants and patent attorneys;
- skill improvement courses for IT specialists;
- providing the second university degree in the "Intellectual Property" specialty.

With the aim of sharing experience and best practices of the leading foreign offices (functioning as ISA/IPEA) in matters relating to examination of applications for inventions, in particular patent searches using various search systems and foreign commercial resources, search reports preparation, emergence of new databases, use of the IPC and other classification systems, the matters of legislation development in the industrial property sphere in the countries of the world, respective measures have been taken to promote studying of such experience, its implementation into the activities of the state system of intellectual property legal protection and improvement of employees' skills, first of all examiners' skills.

Alongside this, the records of the skills improvement events are kept and monthly reports about them are prepared according to the set standard forms and forwarded to the Staff Office to be further processed, summarized and become the basis of respective proposals.

(a) acquire and maintain the necessary experience and skills

Newly recruited examiners are assigned tutors from among the experienced senior examiners having the signing authority. Such tutors organize trainings (the training

program is designed to last a year) and check the work performed by junior examiners.

After the examiner's competence and skills have undergone rigorous assessment, the examiner is entrusted with the signing authority, which enables him to make independent decisions about the invention's conformity with the patentability conditions and perform patent information searches for this purpose.

Their decisions are now subject only to internal control (selective control by the Quality Control Unit), along with this 100 % of decisions concerning the refusal in providing legal protection are, however, to be checked by the Head of the Examination Division.

The training of all examiners is organized on an ongoing basis in the form of performing and documenting patent information searches and examination case studies.

The reference and information section of the "Inventions" AS provides all examiners with permanent access to the following materials:

- presentations and training materials, interpretations, instructions and methodologies of examination and search techniques;
- comments on specialized matters concerning carrying out searches in chemistry, pharmaceuticals and molecular biology, electronics, etc.;
- internal training programs and clarifications of the matters of EPOQUE Net system use (based on the materials presented by EPO);
- training and clarification materials on the IPC and IPC reclassification matters;
- information and training materials concerning the Common Patent Classification (CPC).

The materials of trainings and workshops organized on the Ukrpatent level, as well as external seminars and conferences held, in particular, by the search systems providers (STN, EPOQUE Net, Reaxys) and meetings of examiners with representatives of respective industrial sectors are accessible through the Intranet Portal.

Great attention is paid to training examiners to perform searches via EPOQUE Net. Examiners regularly attend webinars and other on-line training events organized by the EPO, as well as in train-the-trainer seminars in order to be able to share the obtained knowledge with other examiners using EPOQUE Net.

In order to make the use of EPOQUE Net more advantageous, a permanent Working group was created, whose members exchange personal experience, process the information received on the EPO seminars and training sessions for EPOQUE Net users, develop the ways to improve the patent search strategy with the due account of the experience of the EPO and world leading patent offices.

Examiners constantly receive information via e-mail about free-of-charge trainings and webinars on Patent Cooperation Treaty (PCT) matters held by WIPO, webinars

organized by the EPO to highlight the news and latest developments in the patent information services field and new patent information systems and services.

(vi) are fully aware of the importance of complying with the quality criteria and standards

Thanks to the above-mentioned forms of training and provision of access to the mentioned materials, examiners are constantly knowledgeable of the important matters concerning maintaining the quality criteria and quality standards when performing examination and patent information searches.

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

See 21.08, 21.09, 21.12.

to deal with demand

Ukrpatent possesses the necessary resources, the principal ones of which are the following: skilled personnel with the appropriate level of expertise; optimal infrastructure ensuring compliance with the requirements for services; maintained and controlled operation environment providing the proper material and social conditions for the work, motivation, demands compliance, and staff performance.

The Ukrpatent management constantly performs the compliance analysis of the level of provision/sufficiency of these resources with current needs in quality examination and search, depending on the workload of examiners, based on the results of review of the monthly reports by the heads of the respective structural divisions. Such analysis results in decisions and corrective (remedial) actions.

comply with the quality standards for search and examination

The Director for Examination of Ukrpatent represents the management as the person responsible for supporting the process of fulfillment the requirements regarding standards in patent search and examination.

The procedure of the quality control of the examination and searches is described in details in Section 21.12.

In order to control the resources used for patent searches, improvement, quality enhancement and adherence to unified methodological approaches when performing patent searches, a respective order of Ukrpatent approves the composition of information resources for carrying information search in the course of substantive examination of applications for inventions; in particular, the list of the Ukrpatent in-house electronic information resources and alternative free Internet resources and the

list of foreign commercial information resources providing Ukrpatent with access to the PCT Minimum Documentation (patent documentation and non-patent literature) via the Internet under the concluded agreements are defined and they are obligatory for use.

The works intended for regular replenishing the in-house electronic information file, as well as providing continuous use of the designated foreign commercial Internet resources within the agreements signed with WIPO, the EPO and foreign providers are carried out on the on-going basis.

Additionally, information concerning the free publicly available Internet resources (IPR databases, scientific and technical databases and reference resources) is systematically monitored, updated and placed on the Ukrpatent web resources.

3. MANAGEMENT OF ADMINISTRATIVE WORKLOAD

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

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

With the aim of ensuring high-quality and timely examination and searches, an automated quality control system has been implemented within the "Inventions" AS enabling to monitor:

- the timeliness of consideration of applications for inventions by examiners;
- the timeliness of search performance;
- the proceeding state of the applications considered by each examiner.

This system enables the management of the examination division to receive complete on-line information on the examiners' compliance with deadlines of the initial application consideration, providing responses to the applicant, generation of preliminary conclusions and requests, drafting search reports, and to take any necessary corrective and preventive measures to ensure no deviations from the set procedures occur.

Beside this, a monthly statistical report is generated by an authorized person based on the results of such monitoring of the application processing, which is subsequently forwarded for the consideration of the Head of the Examination Division and analyzed in the course of a working meeting held by the Director for Examination. Summarized analytical data and decisions made on such meetings are brought to the attention of the heads of examination units included to the Examination Division so that respective measures can be taken by them to provide a more effective monitoring of examiners' workload and application distribution.

All examiners also have access to such statistical data and are able to control the order of applications consideration and searches.

4. QUALITY ASSURANCE

21.12 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:

(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 channelling 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.

All procedures connected with acquisition of rights (from application filing to patent grant or refusal) including all measures taken to provide quality, are documented and stored in the "Inventions" AS. This ensures the possibility of quality provision process monitoring on the whole by using the current state of application processing.

Each examination unit is responsible for the quality of examination in its particular industrial field. The quality guarantee system includes peer review carried out by senior examiners and quality checks performed by heads of examination units, the Quality Control Unit and the Examination Division Head.

To settle complicated controversial issues, the Ukrpatent Expert Board on Examination of Inventions and utility Models Applications is created within the Examination Division, the Expert Board Regulations and its members are approved.

A quality support system has been implemented and maintained. The aim of the system is to provide a unified approach to the examination and search processes in all examination units in the industrial fields. To this effect, respective control is carried out within the Examination Division by the **Unit for Quality Assurance and Improvement of Examination of Applications for Inventions, Utility Models and Topographies of Integrated Circuits (Quality Control Unit)** or by members of the Quality Coordination Board appointed to fulfill the functions of quality provision. These individuals are the most experienced examiners having significant expertise in performing searches using various search systems and databases. Such control is provided by randomized and routine checks of search reports, optimal use of search systems and databases, suitability of opposition of the retrieved documents and assessment of their relevance.

All search reports are first checked by tutors, then randomly by heads of units in the industrial fields, the Quality Assurance Unit and the Examination Division the Head

(Deputy Head). The checks of the next level are provided by a member of the Quality Coordination Board.

The process of report quality provision includes the following steps:

- examiner's self-checking with the help of checklist where the list of quality requirements is given;
- routine automated checking by tutoring senior examiners or heads of units in the industrial fields;
- randomized automated checking by the **Quality Assurance Unit** or a member of the Quality Coordination Board or the Expert Board. All final decisions about non-compliance of an invention with the patentability conditions are subject to 100% check by the Quality Control Unit and the Head/Deputy Head of the Examination Division.

When considering an application for invention, an examiner must follow current legislation and regulatory documents. In the process of examination and searches the "Inventions" AS is used for both national and PCT applications for inventions.

In order to ensure the timely consideration of applications for inventions and search performance, automated control of deadlines for necessary actions connected with the applications and search report generation, as well as control of initial application consideration deadlines and of responses to requests and examiners' preliminary decisions has been implemented.

To ensure the quality in this automated system, the functions of necessary actions performance monitoring provision have been implemented.

In order to achieve a higher level of examination and search quality and to ensure the highest possible level of correspondence of applications subject matter to the specialization of examination units in the industrial fields, automated distribution of applications to examiner groups has been implemented (using topical fields which include the combinations of IPC classification symbols and keywords).

Based on the results of checking of search reports, requests and preliminary decisions, the controlling person must pass a resolution and in case of need has the right to return respective documents for improvement. For quality control improvement and for training purposes an automated module is implemented in the "Inventions" AS for consultations by heads of units in the industrial fields, by the Quality Control Unit specialists.

At the end of each month all such resolutions are collected and analyzed in order to detect typical mistakes. After the mentioned matters have been studied, an appropriate kind of training is carried out both for examiners and for heads of examination units in the industrial fields. The reference and information section of the "Inventions" AS provides access to the methodical materials elaborated on the basis of such trainings.

In 2018 internal quality control was rather intensive. Analysis of data of the "Checked Documents" module in the "Inventions" AS as of November 15, 2018 shows about 51 461 internal technological checks of examination documents. Intensiveness of checks depended on how time-consuming, important and complicated the documents were.

In 2018 modernization of the "Inventions" AS was in progress. This modernization resulted in development of new software modules which provide for additional possibilities for quality control system of the applications examination in the "Inventions" AS and carry out the following new functions:

- transfer of utility model applications to the quality control unit for providing consultations to the examiners;
- viewing of the applications received from an examiner who requests consulting;
- keeping track of recommendations, comments and resolutions of the consultant in the "Inventions" AS;
- transfer of the application together with the recommendations, comments and resolution to the examiner who requested consulting;
- report generation for a given period, which reflects appeals of examiners, application numbers, provided recommendations, comments, resolutions and time spent on the consultation of examiners;
- approval of the reports and their storage in the Inventions AS.

After the initial analysis of such quality-related issues the most significant ones requiring correction actions in order to ensure the compatibility to quality standards are selected. In case of need, the selected issues are considered at the meetings of the Expert Board or the Quality Coordination Board.

To ensure the quality of examination and searches, all examiners have on-line access to the Patent Cooperation Treaty (PCT), Regulations under the PCT, PCT Administrative Instructions, respective WIPO standards and all necessary regulatory acts and guidelines via the reference and information section of the "Inventions" AS.

5. COMMUNICATION

Inter-Authority communication:

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

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

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

- (a) helping identify and disseminate best practice among Authorities;*
- (b) fostering continual improvement; and*

(c) providing for effective communication with other Authorities to allow for prompt feedback from them so that potential systemic issues can be evaluated and addressed.

The person responsible for information exchange between Patent Offices is:

On the side of the Ministry:

Iryna Matsiuk, Head, Sector of Cooperation with National and International Institutions in IP Sphere, Department for Intellectual Property of the Ministry,

Tel.:(+38044) 596-67-52; *e-mail: imatsiuk@me.gov.ua*

On the side of Ukrpatent:

Yuriy Kuchinsky, Head, Unit for International Relations and Public Relations, Ukrpatent

Tel.:(+38044) 494-0604; *e-mail: yk@ukrpatent.org*

Olena Danilova, Head, Unit for Quality Assurance and Improvement of Examination of Applications for Inventions, Utility Models and Topographies of Integrated Circuits, Ukrpatent

Tel.:(+38044) 494-05-39; *e-mail: o.danilova@ukrpatent.org*

Ukrpatent's address: 1 Hlazunova Str., Kyiv-42, 01601, Ukraine

Phone: +380 (44) 494-05-05 Fax: +380 (44) 494-05-06 office@ukrpatent.org

Communication and guidance to users:

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

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

(i) – (ii) Appeal examination and correction of irregularities, as well as proposals on corrective and preventive measures to be taken are carried out/provided by the Intellectual Property Legal Support and Economics Division. In complex cases, when

it is necessary to make corrections and several units are involved, a meeting of the directors supervising the relevant areas or a meeting of the Quality Coordination Board is held and a task force is formed. Compliance with the deadlines set for the execution of documents and the provision of responses to queries or appeals are controlled by the Assignments Control Sector.

In addition, in order to determine the demands and satisfaction level of users and persons concerned on such matters as quality service, accessibility and completeness of information, procedure and terms of solving any problems appearing at Ukrpatent, the secure feedback system with all possible modern means, in particular telephone/facsimile communications, regular and electronic mail communication etc.

Each applicant is able to communicate with the examiner face-to-face during the examination procedure or to communicate with him/her through telephone/fax, electronic mail etc. All necessary information is delivered to the applicant on a mandatory basis.

All appeals of applicants are fixed in the corresponding electronic registry and the terms of making responses are under control of the Assignments Control Sector, which submits weekly reports regarding the results of this control to the management.

During conferences, symposiums, seminars, round-table discussions, meetings and other events on intellectual property issues Ukrpatent conducts surveys (using questionnaires etc.) among the participants asking them to estimate the activity of Ukrpatent and to give their proposals regarding the quality improvement of the Ukrpatent services or proposals on the issues which need to be settled or are to be discussed within the following similar events.

Based on the analysis of the information received from applicants and public, the management of Ukrpatent takes measures to correct these mistakes (corrective actions) and to prevent further mistakes (preventive actions), in particular by providing training for examiners, giving clarifications on problematic matters and suggestions regarding the quality work improvement of examiners, etc.

(iii)

To familiarize users with the information and regulations relating to patent search and examination, the general information concerning the process of obtaining the rights to inventions under PCT with relevant links to regulations and indexes on the WIPO website is provided on the Ukrpatent web-site. Also, interactive databases and information and reference systems, containing the texts of legal acts, including international agreements, and other information, necessary to draft and file an application, are provided for on the Ukrpatent web-site.

Users can obtain all relevant information and advices relating to filing and examination of the national and international applications under PCT by addressing the Division of Patent Information Services, Consultations and Innovation Activity

Promotion or the Unit of International Applications for Inventions and Utility Models.

(iv)

Users have an opportunity to get familiar on the Ukrpatent Web-site with the Annual Reports of the SIPS on its activities in the sphere of legal protection of intellectual property for the years 2003-2016 as well as with three Annual Technical Reports on Information Activities in 2017 in the sphere of industrial property prepared for WIPO by Ukrpatent.

Ukrpatent's (annual) plans of works on the realization of the principle directions and priority goals of its activity, including the quality sphere, are available on the internal Ukrpatent web-site.

Users are also informed on the matters of examination quality provision in the course of scientific and practical conferences and seminars.

21.16 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

Exchange between WIPO and the Ministry and Ukrpatent is carried out via mail, facsimile communication and e-mail.

Responsibility for maintaining the communications lies with the Sector for Cooperation with National and International Institutions in IP Sphere of the Department for Intellectual Property of the Ministry and the Unit for Quality Assurance and Improvement of Examination of Applications for Inventions, Utility Models and Topographies of Integrated Circuits of Ukrpatent. The whole volume of incoming foreign correspondence and documents received by Ukrpatent from WIPO (directives, circulars, letters, notifications, and other documents), the EPO, foreign patent offices, other foreign companies, organizations and institutions (primarily in English, but also in French, German and other languages) is processed under the set procedure, which provides that every document:

- is registered in the general Electronic Document Management System (EDMS) which operates within the internal document flow (automatic generation of information according to the incoming document number and date, incoming registration number, addressee organization, responsible implementer, hands-on implementer, assigned due date of the given directive, order etc);
- undergoes information and analytical processing, during which the contents of the document is studied and analyzed preliminarily, the cover letter (if any) is translated, the received documents are selectively translated, a respective summary is prepared.

Information and analytical processing of the document is completed by the preparation of an Information notice under the set form (to which copies of the necessary documents are annexed or the reference to their storage place is given), which is then submitted to the Director General of Ukrpatent through the EDMS.

Having considered this notice, the Director General of Ukrpatent passes a resolution-instruction to the Directors (considering their scope of responsibilities), appointing responsible executors and the deadline for fulfilling the instruction, following which all the information is recorded in the EDMS and the document is passed to the Directors (responsible executors) and preparers.

Further, if necessary, translation of the selected parts of a document or entire document is made.

The described procedure of processing the incoming document flow at Ukrpatent ensures their prompt consideration and systematic control of fulfillment of instructions connected therewith by the respective division within the framework of the EDMS; in order to provide such control, the EDMS provides automatic generation of information by the number and date of the incoming document, incoming registration number, sender, responsible executor, immediate executor, appointed deadline for the given instruction etc.

6. DOCUMENTATION

21.17 Explanatory note: The QMS of the Authority needs to be clearly described and implemented so that all processes in the Authority and the resulting products and services can be monitored, controlled, and checked for conformity. This is done in the documents that make up the Quality Manual of the Authority (see paragraph 21.18).

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

21.18 The 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 QMS of Ukrpatent has been developed and implemented according to the ISO 9001:2008 standard requirements and applicable legislative and regulatory requirements and is applied to the activities of all structural divisions and responsible executors included into the QMS.

The QMS is applied to:

– receipt and examination of applications for IPR as to their compliance with the conditions of legal protection provision;

- information support of the operation of the state industrial property protection system, including creation, updating and operability assurance of the patent information file necessary for examination, as well as of the reference and search tools thereof;
- providing physical persons and legal entities with information on IPR;
- consideration of oppositions and complaints concerning the issuance of titles of protection and other addresses in the IPR protection-related matters.

The process approach has been applied to the QMS development, implementation, operability assurance and improvement. The processes sequence and interaction, the efficiency criteria and process management means have been defined; the QMS processes and service quality monitoring has been provided on all relevant stages of the QMS processes implementation. The QMS processes are divided into the following groups:

- processes related to the management activities and documentation management;
- processes of provision of resources to the QMS;
- processes of the services life cycle;
- measuring, analysis and improvement processes.

The Quality Manual sets out the requirements to the QMS of Ukrpatent and contains its description.

The QMS documentation is presented both on paper and electronic carriers.

Information concerning the QMS documents of Ukrpatent, procedures and processes, and links to the relevant information provided by WIPO are also available on the Intranet Portal.

Examiners working with the "Inventions" AS are able to receive the necessary information at any time via the annexed instructive and regulatory materials. The users may address the reference and information section of the "Inventions" AS. When the reference or regulatory documentation is updated, the latest versions of the documents become available for all users of the "Inventions" AS simultaneously.

21.19 Indicate whether the documents making up the Quality Manual 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 QMS documentation of Ukrpatent comprises the following documents:

- Ukrpatent context;
- quality policy;
- quality objectives;
- quality manual;
- the QMS documented methodologies;
- provisions (concerning structural divisions, management bodies, operations etc.);
- instructions (staff, occupational safety, safe operation, operational etc.);
- schedules;
- structure charts;
- records (protocols);
- regulation documents of external origin;
- other documents used in the QMS processes.

The following QMS documented methodologies have been developed and implemented at Ukrpatent:

- methodology № 01-QMS “Control of quality management system documents”;
- methodology № 02- QMS “Control of quality management system records (protocols)”;
- methodology № 03- QMS “Quality management system internal audit”;
- methodology № 04- QMS “Control of nonconforming services”;
- methodology № 05- QMS “Corrective action”;
- methodology № 06- QMS “Risk control. Definition, identification and evaluation”;
- methodology № 07- QMS “Monitoring of the Quality Management System processes”.

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

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

- (xi) *actions taken re. preventative action; and*
- (xii) *search process documentation as set out in Section 7.*

According to the ISO 9001 standard requirements, Ukrpatent provides retaining and maintenance of the following documents:

- Quality Manual;
- procedures and work instructions for quality provision;
- management control results;
- records concerning personnel training;
- records concerning staff qualification and experience;
- reports on improvement of examiners' skills based on the results of conferences and seminars;
- records on processes' conformity with the requirements;
- records on control of the requirements related to the product;
- records on corrective and preventive action;
- records on actions taken in relation to nonconforming products;
- records on QMS control;
- records on the results of patent search and patent examination for each patent application;
- summarized reports on routine controls of the search report and examiners' decisions quality.

7. SEARCH PROCESS DOCUMENTATION

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

The Authority should indicate

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

- (c) *which special cases are documented and whether records are kept denoting any:*
- (vi) *limitation of search and its justification*
 - (vii) *lack of clarity of the claims; and*
 - (viii) *lack of unity.*

(a)

A patent search report comprises the following information:

- information concerning the observance of the invention unity requirement;
- invention claims considered in the course of the search;
- classification of the invention subject matter (using the IPC symbols);
- search area (using the IPC symbols);
- patent documentation and non-patent literature databases;
- keywords, word and IPC symbols combinations used in the course of the search;
- in case of lack of the invention unity, a special notice is provided concerning the group of inventions considered in the course of the search;
- special notices on the amended claims considered in the course of the search;
- indication of the date and person performing the search.

(b)

The records of the search process are stored in the Search Portal and "Inventions" AS, as well as in the search systems used by examiners, namely EPOQUE Net, DWPI via EPOQUE Net, STN etc.

The search history information, in particular search subject matter, query texts, lists of retrieved documents, marked viewed documents, is automatically stored on the Search Portal.

This information is then stored indefinitely and allows both performing internal control of the quality of searches carried out by examiners and using search results for further work.

The list of relevant documents obtained as a result of the search performed via the Search Portal can be transmitted to automatically generate the search report via the "Inventions" AS.

The Search Portal provides for the statistical data generation, in particular concerning the databases used, examiners which performed searches, the number of search queries and documents viewed.

These statistical data and search history data for every search performed are available to the persons carrying out the internal control.

8. INTERNAL REVIEW

21.22 Explanatory note: The Authority should report on its own internal review arrangements. These reviews determine the extent to which it has established a QMS based on the model of Chapter 21 and the extent to which it is complying with the QMS requirements and the Search and Examination Guidelines. The reviews should be objective and transparent to demonstrate whether

or not those requirements and guidelines are being applied consistently and effectively and should be undertaken at least once a year. With reference to point 21.08 of this template, the Authority may provide additional information on its internal review arrangements under this section if it so wishes.

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

Internal QMS audits are carried out twice a year. External audit is undertaken yearly. The audit aim is to confirm the QMS conformity with the ISO 9001 standard.

9. ARRANGEMENTS FOR AUTHORITIES TO REPORT TO THE MIA

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