

Patent Cooperation Treaty (PCT)

Common Quality Framework for International Search and Preliminary Examination

REPORT ON QUALITY MANAGEMENT SYSTEMS

prepared by ROSPATENT

Summary of changes compared to the 2017 QMS Report

- *Structural change. Two new structural units were established in FIPS: Quality Monitoring Center, which includes five divisions, and International Cooperation Center, which includes three divisions.*
- *A new FIPS internship program was implemented, which is designed to attract new specialists and develop their skills to perform patent examination.*
- *Access to additional databases Reaxys, Embase and QUESTEL-ORBIT has been provided.*
- *Measures to improve quality and timely issue of the PCT reports. Monthly preparation of reference notes for each examining division and their supervisors was introduced in order to prevent deficiencies in PCT reports and non-compliance with the time-limits for their submitting to the International Patent Cooperation Division for quality check.*

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

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

INTRODUCTION (PARAGRAPHS 21.01 - 21.03)

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

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

Each Authority should then provide at least the information indicated in the descriptive boxes, under the following headings

Abbreviations:

ROSPATENT - Federal Service for Intellectual Property

FIPS - Federal State Budgetary Institution "The Federal Institute of Industrial Property", under ROSPATENT

RGAIS - Federal State Budgetary Institution for Higher Education "The Russian State Academy of Intellectual Property", under ROSPATENT

References to the legislation relating to quality management system besides Chapter 21 of the Guidelines.

The issues of granting legal protection to the results of intellectual activity, in particular to the inventions, are regulated by Part IV of the Civil Code of the Russian Federation (hereinafter referred to as the Code), which was put into force by the Federal Law № 230-FZ as of 18.12.2006 "On putting into effect Part IV of the Civil Code of the Russian Federation" from January 1, 2008 (as amended).

Since October 1, 2014 the Federal Law № 35-FZ as of March 12, 2014 "On amendments to Parts I, II and IV of the Civil Code of the Russian Federation and certain legislative acts of the Russian Federation" has been in effect. According to Article 3 of said law Part IV of the Code has been amended with an aim to, inter alia, increase the patent quality and legal protection reliability, as well as to harmonize the material and procedural principles regulating the protection of inventions with the international standards, primarily with the standards of the European Community (EC).

The functions of the federal executive body for intellectual property are entrusted to ROSPATENT.

The authorities of ROSPATENT related to the receipt, registration of the applications for inventions, examination and patent granting (in the framework of provision of a state service) are provided by the Resolution of the Government of the Russian Federation № 218 as of March 21, 2012 (as amended).

ROSPATENT is under the jurisdiction of the Ministry of Economic Development of the Russian Federation.

In 2016 a set of by-law regulations governing the provision of a state service related to consideration of applications for invention (hereinafter by-law regulations) was adopted by the orders of the Ministry of Economic Development № 315 and 316 as of May 25, 2016:

The Administrative Regulations on providing by the Federal Service for Intellectual Property a state service on state registration and grant of a patent for invention, a duplicate thereof (hereinafter Administrative Regulations).

The Rules of compilation, filing and processing of documents being a basis for exercising legally significant actions on state registration of inventions, and the forms thereof (hereinafter – the Rules).

The Requirements to the application documents for patent granting for invention (hereinafter – Requirements).

The composition of the information of the patent application for invention, published in the Official Bulletin of ROSPATENT.

The information search procedure within the substantial examination of the patent application for invention and providing a report thereon.

The order and terms of informing an applicant on the results of information search on the patent application for invention and publication of a report on such search.

The terms and conditions of information search on the patent application for invention upon applicant's or third persons' request and providing information on the results thereof.

The composition of the information on grant of a patent for invention published in the Official Bulletin of the Federal Service for Intellectual Property.

The composition of the information in a patent for invention.

The form of a patent for invention.

18 standard forms of request and petition were approved that can be filed by an applicant upon his own initiative within the processing of application at ROSPATENT.

The aforesaid documents entered into force in August 2016.

The purpose of regulation within the framework of the Administrative Regulations is to provide patent grant procedure optimization, clear regulation of the order and terms of exercising administrative actions. The Rules and the Requirements reflect new requirements to application documents, as well as approaches on industrial applicability verification, sufficiency of the disclosure, novelty of the invention based on amendments to the Civil Code.

The list of requirements for the examination of applications, comprising the ones filed through the Patent Cooperation Treaty, including the information search, is established by the Code and by the by-law regulations.

The handling of applicants' complaints to ROSPATENT decisions taken on the application for invention, to illegitimate actions (inaction) of the officials in connection with the state service provision, is regulated by a separate Federal Law № 210-FZ as of July 27, 2010 "On organization of state and municipal services provision" (as amended). The rules of filing and processing of the complaints are established by the Resolution of the Government of the Russian Federation № 840 as of August 16, 2012 (as amended).

The processing of the requests of the applicants, rightholders and other persons on other issues related to the activities of ROSPATENT, are regulated by the Federal Law № 59-FZ as of May 2, 2006 "On the order of consideration of the requests of the citizens of the Russian Federation" (as amended).

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 is determined by the Statute of ROSPATENT approved by the Resolution of the Government of the Russian Federation and the Public Declaration of goals and objectives of the ROSPATENT for the year of 2017 (http://www.rupto.ru/about/opengov/publ_dec_2017.pdf), 2018 (https://rupto.ru/content/upload/files/publ_dec_2018.pdf). The Director General of ROSPATENT is responsible for the development of QMS and policy in this field.

(b), (c) Supervision of issues related to functioning and improvement of QMS is referred to the competence of Mrs. Kiriy L.L., Deputy Director General of ROSPATENT.

The organizational structure of QMS includes the following divisions:

1) Department for the Provision of State Services of ROSPATENT. Management of the department is assigned to Mr. Travnikov D.V., Director of the Department for the Provision of State Services of ROSPATENT.

2) In 2018, structural and personnel changes have taken place in FIPS subordinated to ROSPATENT.

On the basis of the Department for Quality Monitoring, a Quality Monitoring Center was established, which included five divisions:

- Division for general issues of public services provision;
- Division for support of the provision of public services related to the objects of patent law;
- Division for support of the provision of public services related to the means of individualization;
- Division for control of processes and results of the provision of public services and ISO certification;
- Information service and consulting sector.

~~Department~~ The Quality Monitoring Center deals with the general issues of the quality control, including:

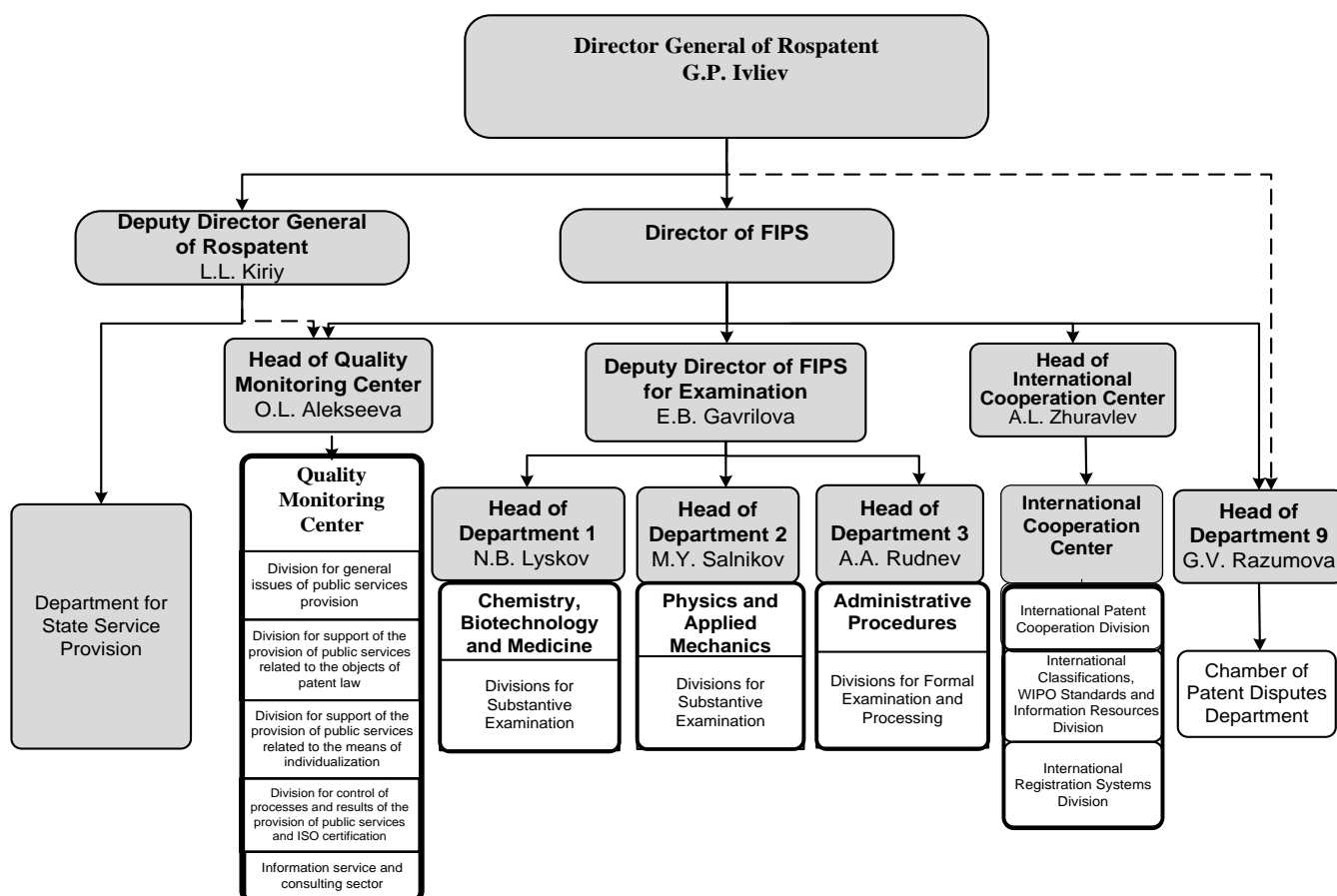
- providing systematic, including operational, and methodical support to examination divisions;
- monitoring the quality of public services, in particular, monitoring:
 - o functioning of the quality management system,
 - o actions and documents prepared by the examiners and other FIPS employees in the implementation of FIPS administrative procedures and in case of the complaint investigation as well,

- timing of the administrative actions;
- development of proposals on organizational, methodological, technological, informational, educational measures aimed at elimination of violations identified during monitoring and their causes;
- complaints investigation for providing public services and their analytical processing;
- analysis of the FIPS activity quality indicators.

The management of the Center is assigned to Mrs. Alexeeva O.L., Head of the Center.

3) “Chamber of Patent Disputes” department dealing with objections to the decisions taken on the results of examination of applications for inventions. The supervision over the Department work is carried out by Mrs. Kiriy L.L., Deputy Director General of ROSPATENT, and by ~~Zubov Ju. S.~~, FIPS Director. *In 2018 FIPS has been headed by Zubov Ju. S.*

4) International Patent Cooperation Division dealing with quality check of the international search reports, written opinions and international preliminary examination reports. The head of Division is Mrs. Popova L.I. *The division is the part of the International Cooperation Center, established in 2018. The management of the International Cooperation Center is assigned to Mr. Zhuravlev A.L., Head of the Center.*



The last direction in the quality management system is connected with the functioning of the ROSPATENT Quality Council headed by Mr. Ivliev, Director General of ROSPATENT.

The ROSPATENT Quality Council was established in 2016. The Quality Council consists of all leading specialists of ROSPATENT and FIPS subordinated to ROSPATENT, including the specialists of the Department of legal representation, who represent the interests before the Intellectual Property Court, where ROSPATENT decisions are contested.

The main tasks of the ROSPATENT Quality Council are:

- assurance of uniformity of the practical application of the Civil Code and by-law regulations, in particular, during the examination of the applications for inventions;
- establishment of objectives for the control of completeness and quality of the state services, analysis of the control results and coordination of the actions aimed at quality upgrade.

During the meetings of the Quality Council the current outstanding issues are discussed, and decisions are taken at the highest level to be followed in practice by subdivisions. The Records of the Quality Council meetings are published on the official website of ROSPATENT (http://www.rupto.ru/about/consult/sovet_po_kachestvu) available for the open access.

The decisions of the Quality Council are obligatory for all FIPS subdivisions.

~~In 2016 structural and staff changes took place in FIPS subordinated to ROSPATENT.~~

~~Mr. Zubov Ju. S. was appointed to the position of FIPS Director. Mrs. Razumova G. V. was put at the head of the Division "Chamber of Patent Disputes".~~

~~In 2016 the work on establishing Novosibirsk FIPS Division (Novosibirsk) which main task will be the examination of applications for utility models, was initiated. In 2017 the established Novosibirsk FIPS Division performs its functions.~~

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

| Chapter 21 requirement | | | | Extent of compliance | | |
|------------------------|--|-----|---------------------------------------------------|----------------------|------|----|
| | | | | full | part | no |
| 21.04 | | (a) | Quality policy availability | ✓ | | |
| | | (b) | Identified roles and names for QMS responsibility | ✓ | | |
| | | (c) | Organizational chart availability | ✓ | | |
| 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 | ✓ | | |

| Chapter 21 requirement | | | | Extent of compliance | | |
|------------------------|-------|-----|------------------------------------------------------------------------------------------------------------------|----------------------|------|----|
| | | | | full | part | no |
| 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 are performed | ✓ | | |
| | | (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 to paragraph 21.24 | ✓ | | |
| | | (e) | recording the results | ✓ | | |
| 21.10 | | | Assurance of monitoring and adaptation of 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) | | Availability of Infrastructure to provide a quantity of skilled administrative staff | | | |
| | | (a) | at a level that supports the technically qualified staff | ✓ | | |
| | | (b) | for the documentation record | ✓ | | |
| | (iii) | | Ensuring appropriate equipment to carry out S&E | ✓ | | |
| | (iv) | | Ensuring documentation according to Rule 34 | ✓ | | |
| | (v) | (a) | Instructions to help staff understand and act according to the quality criteria and standards | ✓ | | |
| | | (b) | Instructions to follow work procedures accurately and they are kept up-to-date. | ✓ | | |
| | (vi) | (a) | Training and development program to ensure and maintain necessary skills in search and examination | ✓ | | |
| | | (b) | Training and development program to ensure awareness of staff to comply with the quality criteria and standards. | ✓ | | |

| Chapter 21 requirement | | | | Extent of compliance | | |
|------------------------|-------|-----|---------------------------------------------------------------------------------------------------------|----------------------|------|----|
| | | | | full | part | no |
| | (vii) | (a) | System in place for monitoring resources required to deal with tasks | ✓ | | |
| | | (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 channeling feedback to staff | ✓ | | |
| | (ii) | | System for measurement of data and reporting for continuous improvement | ✓ | | |
| | (iii) | | System for verifying the effectiveness of actions taken to correct deficient S&E work | ✓ | | |
| 21.14 | | (a) | Contact person helping to identify the best practice between Authorities | ✓ | | |
| | | (b) | Contact person assisting continual improvement | ✓ | | |
| | | (c) | Contact person providing for effective communication with other Authorities for feedback and evaluation | ✓ | | |
| 21.15 | (i) | (a) | Appropriate system for handling complaints | ✓ | | |
| | | (b) | Appropriate system for taking preventive/corrective actions | ✓ | | |
| | | (c) | Appropriate system for offering feedback to users | ✓ | | |
| | (ii) | (a) | A procedure for monitoring user satisfaction & perception | ✓ | | |
| | | (b) | A procedure for ensuring their legitimate needs and expectations are met | ✓ | | |
| | (iii) | | Clear and concise guidance on the S&E process for the user | ✓ | | |
| | (iv) | | Indication where and how the Authority makes its quality objectives publicly available | ✓ | | |
| 21.16 | | | Established communication with WIPO and designated and elected Offices | ✓ | | |
| 21.17 | | | QMS of Authority clearly described (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 | ✓ | | |

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

| Chapter 21 requirement | | | | Extent of compliance | | |
|------------------------|--|--|------------------------------------------------------------------|----------------------|------|----|
| | | | | full | part | no |
| 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), (b) The effectiveness of QMS is ensured by:

- the implementation of measures directed on improvement of examination quality, optimization of applications processing and new information technologies, which are included in annual and long-term plans;
- execution control of planned measures by the Director General of ROSPATENT;
- monitoring of FIPS activity results;
- recording and analysis of ROSPATENT staff proposals and development of measures for quality improvement;
- carrying out preventative current, planned and extraordinary control of the quality of searches and examination;
- applying control system for registration of the users' complaints and development of measures for prevention of infringements.

Development of QMS is provided by:

- proposals on improvement of the Russian Federation legal system for the compliance with the international standards;
- activities on methodical support of search and examination.

In 2016 ROSPATENT and EPO agreed within the framework of the signed bilateral cooperation program to exchange information and opinions on the issue of QMS by means of videoconferences. The discussions are focused on the issues of ISO 9001 certification, which will help ROSPATENT to estimate how ISO 9001 standard correlates to ROSPATENT internal quality management system, and how it can be implemented. In accordance with the agreement, in 2017 EPO and ROSPATENT held videoconferences, as well as a meeting on certification issues in accordance with ISO 9001.

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

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

(a), (b) Information about the importance of contractual and normative requirements, including requirements of the PCT concerning the maintenance of quality of international search and international preliminary examination, as well as requirements of QMS is brought to the notice of the staff:

- by reports, regulations and orders of the Director General of ROSPATENT and the Director of FIPS on paper and in electronic form under “Code” network resource accessible to the staff;

- during operative meetings of the Director General of ROSPATENT, the Director of FIPS and the Deputy Director;

- at the meetings of the ROSPATENT Quality Council;

- at a meeting of the FIPS Methodical Council established to resolve problematic issues of the applications examining.

The information on results of inspections of examination quality, new procedures, other information concerning the activity of ROSPATENT and FIPS is sent to the heads of divisions for informing staff and using in its work.

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) Administrative operational inspections are carried out by orders of the Director General of ROSPATENT. The planned inspections of the completeness and quality of a state service provision are carried out according to the rulings of the Administrative Regulations. The inspections are carried out by the Department for the Provision of State Services of ROSPATENT and the **Quality Monitoring Center** department of FIPS, International Patent Cooperation Division, heads of examination departments.

Reports prepared according to the results of inspections are presented to the Director General of ROSPATENT.

(b) The targets of QMS are revised in the course of planning of ROSPATENT activity (preparation of the Public Declaration of tasks and objectives of the Federal Service for Intellectual Property) and plans of ROSPATENT and FIPS activity for the next year based on the parameters of activity of the Office for previous year).

(c) The corresponding information is brought to the staff by issue of orders and instructions, which are distributed to the divisions and published on “Code” network resource.

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).*

Internal inspection of QMS can be carried out in relation both to separate aspects of activity and QMS as a whole (for example for definition its compliance with the requirements of Chapter 21). Such inspections are carried out on the basis of instructions of the Director General of ROSPATENT within the frameworks of other activities planned.

The report on the results of inspection is prepared. Proposals on the improvement of QMS are recorded and studied.

2. RESOURCES

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

Human resources:

- (i) Provide information about the infrastructure in place to ensure that a quantity of staff:
sufficient to deal with the inflow of work;
which maintains the technical qualifications to search and examine in the required technical fields;
and
which maintains the language facilities to understand at least those languages in which the minimum documentation referred to in Rule 34 is written or is translated
is maintained and adapted to changes in workload.*
- (ii) Describe the infrastructure in place to ensure that a quantity of appropriately trained/skilled administrative staff is maintained and adapted to changes in workload:
at a level to support the technically qualified staff and facilitate the search and examination process, and
for the documentation of records.*

(i) The recruiting of staff for FIPS divisions, personnel inventory and analysis of staff are carried out by Human Resources Division.

FIPS has sufficient staff of the qualified examiners for carrying out of search and examination, as well as sufficient amount of vacancies for correcting number of examiners depending on changes of work volume and subject-matters of the applications filed.

All examiners have higher education (post graduate degree is a great asset) and foreign language skills sufficient to carry out an examination, primarily English.

Carrying out search and examination of the international applications is assigned to the qualified intellectual property examiners.

The examiners have access to the machine translation system (PROMT Professional 7.0) and specialized dictionaries on various subject matters and different languages. At the disposal of examiners there are modern search systems and databases, which allow to perform analytical processing of documents.

In ~~2017~~ 2018 the following was done as concerns the staff:

- continued work on improving the remuneration of labor and bonuses to employees of the examining divisions;
- in order to implement the Government's program on improving the human resources capacity of institutions, labor contracts with FIPS employees in the form of an effective contract have been drawn up, which specify the official duties of employees of the examining divisions, the criteria for assessing the effectiveness of their activities and wages;
- in order to improve the effectiveness of the implementation of personnel policy, to improve the proficiency of the staff, as well as to identify and develop prospective employees in examining divisions, a staff reserve of FIPS employees has been formed;
- *a FIPS internship program was implemented, which is designed to attract new specialists and develop their skills to perform patent examination.*

With respect to staffing levels, it should be noted that in ~~2017~~ 2018 the total number of examination staff was ~~983~~ 1042, of whom ~~622~~ 598 examiners were engaged in international search and international preliminary examination-related work.

International search and international preliminary examination-related work is overseen and the quality of reports is checked by examiners of the International Patent Cooperation Division (number of staff ~~29~~ 33 employees, ~~20~~ 14 of which are examiners dealing with quality check).

(ii) There is sufficient number of personnel for fulfillment of administrative and technological procedures.

Material resources:

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

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

(v) Describe how instructions:

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

to follow work procedures accurately and consistently

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

(iii) The IT infrastructure is provided by:

- ~~the Department for Information Technologies~~ *the Division for applied information systems design and development, and the Division for applied information systems support* dealing with designing, developing and testing of information systems and resources, implementation and support of information systems and resources, preparation of proposals for the development of information technology architecture of FIPS (including the ones for the development of technical processes, information systems and resources, hardware and operating system software).

- the Computer Centre dealing with operation of automated systems, maintenance of computer facilities and software system, providing access to information files.

All examiners maintenance workplaces are computerized.

Since 2008 the automated system of electronic workflow of the PCT applications at the international phase (ELA PCT) has been in operation.

(iv) For carrying out search the examiners have access to a number of the automated search tools, which cover not only the documents included in the PCT minimum documentation specified in the Regulations under the PCT, but also the documents beyond it.

Each examiner has an unlimited access from their workstation to internal search system PatSearch. Full texts of all patent documents of the USSR and Russia since 1924, patent documents of the CIS States, and also files of patent documents of foreign countries and the international organizations, which documentation are included into PCT minimum, are loaded into the system. ~~In 2015, the full descriptions of US patents in text format from 1920 to 1999 were loaded into the PatSearch system. As a result the search through the descriptions of all patents and published US applications from 1920 up to present became available. The DWPI database was included into PatSearch in 2009.~~

The examiners have access through PatSearch system to the Scientific electronic library eLibrary.ru. Additionally the PatSearch system allows redirecting a query to EPO Espacenet search system and to EMBL European Databank of genetic sequences.

The examiners have online access via Internet to updating search resources, including websites of the foreign patent offices (the EPO, the USA, Japan, Korea, WIPO, Germany, etc.).

The sites containing non-patent information, ~~in particular the Science Direct multidisciplinary database, and~~ relating to medicine, pharmaceuticals, chemistry, and biotechnology (for example, database MEDLINE, databases on biotechnology of national library on medicine of the USA and the European Bioinformatics Institute) are accessible to the examiners. *Since 2017, examiners have been granted access to TKDL search system containing information on the traditional knowledge of India.* Examiners also have access from their workstations to reference sites, dictionaries and online translators.

Besides ~~the above~~ freely accessible databases, the examiners have access to commercial databases (~~databases provided by~~ STN International *search systems*, *SCOPUS, Science Direct network, covering both patent and non-patent literature*; Orbit Intelligence, Web of Science, *Reaxys and Embase, QUESTEL – ORBIT, as well as Electronic library of dissertations of the Russian State Library (RSL).* Besides, in 2018 FIPS has got free access to 4 commercial databases (*SCOPUS, Science Direct, Web of Science, QUESTEL - ORBIT*) as part of the “National Subscription” project. ~~search systems, «RZ-VINITI» database of abstracts.~~ Qualified examiners assist in carrying out searches in the specified commercial search systems.

Since October 2017, full access to the databases of Kluwer Law and Business - Kluwer IP Law has been provided.

When necessary, the automated search may be supplemented with traditional search in patent collections on paper or optical disks available at the Collections of the All-Russian Patent and technical Library (FIPS Division). Within interlibrary subscription and electronic document delivery the examiners have a possibility to receive necessary materials on non-patent documentation from 8 largest Moscow libraries.

The examiners are informed of all changes occurring in information search resources, including the new Guidelines for search in information resources. The search guidelines are put on the public segment of the intraoffice computer network.

The information letters on availability of access to information files are distributed to examining divisions.

(v) The description of working procedures and explanation how correctly to carry out thereof is contained in instructions and guidelines approved by the Head of ROSPATENT and/or FIPS. The specified documents are issued on paper and delivered to divisions, and also placed in electronic form at Intranet under “Code” section accessible to divisions of ROSPATENT and FIPS.

The international search and preliminary examination is carried out according to the PCT International Search and Preliminary Examination Guidelines. Examiners also use an internal information search Guideline which regulates the carrying out of search.

During examination, the Guidelines for the Examination of Applications for Inventions are used, which were adopted in 2011 by order of ROSPATENT and developed to provide methodological support for the processing of applications. In the course of its developing the EPO Examination Guidelines and the PCT International Search and Preliminary Examination Guidelines were used to. In 2013 and 2014 the updates and additions to the section of the

Guidelines for examination of applications for inventions related to information search were prepared.

All mentioned Guidelines as well as the list of available Internet sites, are posted on Intranet.

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.

(vi) The examiner's training is based on the Uniform System of Training and Professional Skill Improvement of the FIPS Staff approved by the Order of the Director of FIPS in 2009.

There are the following forms of training.

1. Self training – studying by the employees regulatory legal acts, internal regulatory and administrative documents used in the course of exercising direct employment duties including the use of distance learning according to the programs of the WIPO Academy.

2. Tutorship – individual on-the-job training for assimilation of the profession. Results of this training are supervised directly by the tutor in the process of internal quality review of the documents prepared by new employee.

3. Internal training.

3.1. Training in the divisions in accordance with the quarterly plans developed by the heads of each division. The training is targeted basically on studying new regulatory documents, discussing and analyzing the quality monitoring results.

3.2. Centralized training under the specially developed programs for the examiners and technical staff.

3.3. Regular training of the examiner staff in the skills of carrying out the search is carried out by qualified FIPS specialists. Classification according to the IPC (International Patent Classification) and CPC (Cooperative Patent Classification) training is also conducted.

4. Training based on exchange of experience with other patent offices – traineeships in foreign countries, participation in workshops conducted by the leading experts of the patent offices and organizations, including the EPO Academy and the WIPO Academy.

5. Education in RGAIS subordinated to ROSPATENT.

~~5.1. Education under the programs of improvement of professional skills.~~

5.2. 1 Education under the programs of higher education in the fields of “Jurisprudence” and “Management”.

5.3. 2 Post-graduate course in RGAIS.

6. Training in FIPS under the programs of improvement of the skills of employees. Improvement of professional skills under the program developed by experts and aimed at newly recruited examiners (204 hours) is closely linked with the production process. In addition to the lecture presentation of the theoretical material, practical classes and business games in small groups are organized, taking into account the topics of applications examined by the examiners

under training. Classes are conducted by highly qualified examiners. Training materials are developed on the basis of real situations arising within examination work. During the four-month training the examiner is engaged in the examination of real applications, which helps him to master professional skills already within the training process.

Specialists involved in carrying out an information search and, likewise, specialists involved in the quality control of search use within the PatSearch information retrieval system a search history recording software developed and implemented in 2011.

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.

(vii) With respect to the monitoring (control) of resources, it should be noted that statistics for the reporting periods on all directions of FIPS divisions' activities are permanently collected and analyzed, which allows supervising and planning procedures, including the international search and international preliminary examination. The necessary number of examiners is calculated on the basis of the internal labor standards for maintenance of effective and qualitative fulfillment of the activity.

The Division for Development of Information Resources, Classification Systems and Standards in the IP field and examiners of the divisions regularly monitor the information resources in different fields of science and technology, estimate the value of new sources of information and provide the examiners with an access from workstations (in case of free access), or in special Search Rooms (in case of non-free access). In the process of revision of the International Patent Classification the reclassification of national documents is carried out.

As a result of annual monitoring the fluctuations of the applications relating to different fields of science and technology and correspondingly to different IPC symbols, FIPS administration carries out equal redistribution of the IPC symbols assigned to the examining divisions to avoid the misbalance in the examiners' workload.

In accordance with the Agreement signed in 2013 between ROSPATENT and the European Patent Office (EPO) concerning CPC, since 2016 ROSPATENT has been using CPC as its own internal classification system together with the International Patent Classification (IPC).

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.*

The International Patent Cooperation Division (IPCD):

- records international search and examination requests, prepares the notifications of their receipt, forms application files, initially classifies subject matter for each application and defines the examining division for execution;
- prepares an assignment to appropriate examining division with indication of deadline for submission of reports to the IPCD;
- collects and checks the international search reports, written opinions and the international preliminary examination reports prepared at examining divisions;
- sends the reports after check to WIPO and the applicants.

(i) Control of time-limit is carried out both by the heads of examining divisions and the IPCD.

The intra-automated system ELA PCT, which contains information of the international applications, allows to control the time-limits for preparing international search reports and written opinions.

(ii) Applications and assignments for carrying out the international search and international preliminary examination received by the examining division are distributed by the head of the division taking into consideration the examiners' workload.

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, including the use of any checklists to verify reports before their issue or for monitoring the quality standard as part of a post-issue review process:

- (i) An internal quality assurance system for self-assessment, involving verification, validation and monitoring of searches and examination work:
for compliance with these Search and Examination Guidelines;
for channeling feedback to staff.*
- (ii) A system of measurement and collection of data and reporting. Show how the Authority uses the system to ensure the continuous improvement of the established processes.*
- (iii) A system for verifying the effectiveness of actions taken to correct deficient S&E work, eliminate the causes, and to prevent issues from recurring.*

(i) The following quality assurance scheme of drawing up international search and examination reports is provided in the Office.

The quality of search and examination reports is supervised by the heads of examining divisions.

The International Search reports, written opinions and International Preliminary Examination reports (PCT reports) are checked by examiners of the International Patent Cooperation Division (IPCD).

The drawbacks in PCT report, as a rule, are corrected after discussing thereof between the examiners of the examining division and the IPCD. In case of disagreements, the PCT report together with the opinion of the IPCD (IPCD formalized conclusion reflecting the drawbacks in the PCT report) are submitted to a head of a respective examining division for analysis and possible correction of the PCT report. In case of dissent the head of the examining division with the opinion of IPCD, the final decision regarding the necessity in correcting the PCT report is taken by the supervisor of the examining division.

(ii) IPCD formalized conclusion on the quality of the PCT report is compiled in accordance with the requirements of the Regulations under PCT and the PCT International Search and Preliminary Examination Guidelines. IPCD formalized conclusion is substantially a checklist, in which the following is specified:

- meeting of deadlines;
- correctness of application classification using the current version of the IPC;
- compliance of the fields of search with the claimed subject matter and completeness of the inventive concept and all claimed features coverage;
- if relevant documents are properly identified and characterized with respect to each claim subjected to search;
- if unity of invention is determined correct;
- correctness of claims grouping by examiner where the application was considered as not complying with the requirements of unity;
- if all claims (excluding claims that are not subjected to search) are addressed with regard to novelty, inventive step and industrial applicability;
- complete setting forth of all necessary observations;
- observation of clarity of the claims, the description and the drawings, and whether the claims are based on the description.

~~Quarterly the International Patent Cooperation Division prepares for FIPS management a statistics note on the results of verification of the international search reports, written opinions or international preliminary examination reports prepared by the examination divisions on international applications, as well as a comment for this note. The note contains information on the broken deadlines for submitting report documents, on the drawbacks contained therein and the number of formalized conclusions submitted to the examination divisions. The comment to this note includes a brief analysis of the audit results and identified trends in the monitored parameters.~~

~~The International Patent Cooperation Division makes proposals, in particular, concerning the expediency of training or recommendations for avoiding such defects in search and~~

examination reports and forwards the proposals for consideration by the respective supervisor of the Division—the Deputy Director of FIPS.

Monthly the IPSD provides reference notes for each examining division and their supervisors on the prepared PCT reports. The notes specially emphasize non-compliance by examiners with the time-limits for submitting the PCT reports to the IPCD for quality check. According to the check results, if required, the proposals on training or preparation of recommendations aimed at eliminating the deficiencies identified in the PCT reports are prepared. The proposals are submitted for approval by the Head of the International Cooperation Center and FIPS Deputy Director, who supervises the examining divisions.

5. COMMUNICATION

Inter-Authority communication:

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

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

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

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

(a), (b), (c) Liudmila Popova, head of the International Patent Cooperation Division, email: otd29ch@rupto.ru,

Marina Evdokimova, Head of Technical and Organizational Support Division of Quality monitoring department, e-mail: otd1640@rupto.ru

Elena Sorokina, Deputy Head of the Quality Monitoring Center – head of the Division for general issues of public services provision, e-mail: otd18ch@rupto.ru

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) Consideration of the appeals (including complaints) of the citizens and legal entities in ROSPATENT is carried out in accordance with the following documents, which describe the procedure and requirements for such consideration:

- Federal law "On the order of public appeals handling of the Russian Federation" № 59-FZ as of May 2, 2006 (as amended);
- Federal law "On organization of state and municipal service provision" № 210-FZ as of July 27, 2010 (as amended);
- Rules of filing and processing of the complaints to the decisions and actions (inaction) of the Federal executive bodies and by their officials, federal state employees, the officials of the state off-budget funds of the Russian Federation adopted by the Resolution of the Government of the Russian Federation № 840 as of August 16, 2012 (as amended);
- Administrative Regulations for providing by the Federal Service for Intellectual Property a state service on state registration of invention and grant of a patent for invention, a duplicate thereof, adopted by the order of the Ministry of economic development № 315 as of May 25, 2016, registered with the Ministry of Justice of the Russian Federation as of July 14, 2016;
- Internal instruction for the citizens and legal entities appeals handling.

The applicant is entitled to apply to ROSPATENT and (or) subordinated FIPS with a complaint to the breach of the order of state service provision where he supposes that his/her rights and legitimate interests have been infringed.

A complaint to the breach of the order of state service provision (hereinafter complaint) – is an applicant's or his legal representative's claim to restore or to protect the infringed rights or legitimate interests of the applicant by the body which renders a state service, or by an official who renders a state service.

A complaint is subject to processing by an official vested with authorities to handle complaints, within fifteen business days since its registration.

Any person in his/her appeal may submit proposals or opinions concerning activities of ROSPATENT in accordance with the Federal Law № 59-FZ as of May 2, 2006. Appeals filed to other State Authorities of the Russian Federation involving matters of ROSPATENT jurisdiction are forwarded to ROSPATENT for consideration.

Functions on accounting, analyzing and summarizing the results of public complaints and other appeals handling in ROSPATENT and working out the outcome documents are entrusted to the *Division for general issues of public services provision. Division of training and analysis quality analysis of the Department quality monitoring.*

Registration, accounting and statistical processing of complaints and other requests received by ROSPATENT, are performed by automated system.

In 2012 for comprehensive and timely consideration of the complaints to the breach of the order of state service provision there was adopted a List of FIPS officials authorized to consider the complaints to the breach of the state service provision.

Appeals received by the heads of ROSPATENT and FIPS during personal meeting are subject to registration and further consideration in the same manner as those received by mail.

Upon the results of a complaint consideration ROSPATENT which renders a state service, takes one of the following decisions:

- satisfies a complaint including by cancelling the taken decision, by correcting misprints and errors in the documents issued as a result of state service provision made by the body which renders a state service or by an institution participating in state service provision, by paying back money means which charging is not stipulated by normative legal acts of the Russian Federation, as well as in other forms;

- refuses to satisfy a complaint.

A motivated response on the results of a complaint consideration is communicated to the applicant in writing or at applicant's request in electronic form not later than the day following the date of the decision taking.

The results of the complaint consideration are reported to ROSPATENT, FIPS management.

As a rule, according to the results of a complaint consideration in the Quality monitoring *Center department*, a *position summary* is prepared, which contains the grounds for the complaint, evaluation of their relevance, lawfulness of actions (inaction) of the officials authorized to exercise administrative procedures related to state service provision, proposals for overcoming committed violations and of their reasons. The summary is forwarded for familiarization to the head of the division and to the head of the subdivision to take appropriate measure.

The overall picture of filed complaints is analyzed and is used for the assessment of the activities of FIPS divisions.

The Quality monitoring *Center department* quarterly and by the results of the year prepares a report on the results of complaints handling, which contains information concerning the reasons for complaints, revealed drawbacks, taken measures and actions aimed at the elimination

of the causes of drawbacks and the dynamics of complaints inflow. This information is used in preparation of the relevant section of the annual report on ROSPATENT activities.

In case of identifying drawbacks, which infringe the legitimate user rights, the measures for the restoration of these legitimate rights are taken.

Preventative measures, namely, actions aimed at the elimination of the causes of potential drawbacks identified by users, are accepted without fail. As a rule, the analytical work and the selection of optimal measures are carried out, including the development of technological processes, the preparation of clarifications on the appropriate actions, etc.

The timely and full consideration of citizens' appeals is monitored in accordance with the requirements of the documents referred to in paragraph (i).

Upon the results of a request consideration (including complaints), a written response is sent to a person who has filed the request. Where a complaint has been satisfied, exhaustive measures aimed at elimination of revealed drawbacks are taken.

(ii) The users submit their comments, suggestions and proposals regarding the office work in their appeals. The consideration of the ones includes the assessment from the point of their advisability. If they are deemed advisable, a proposal is drawn up for their incorporation into the work of the office.

During the ROSPATENT conferences and meetings of the Director General of ROSPATENT with patent attorneys, the interventions shall be recorded, comments and suggestions are registered. The comments and suggestions are used in the relevant departments of ROSPATENT and subdivisions of Quality monitoring **Center department** for the preparation of proposals for making amendments in regulatory and methodological documents. The final documents of the events, containing summaries of the statements, comments and suggestions are represented on the ROSPATENT website.

User comments on the projects of various regulatory documents, available on the ROSPATENT website, are taken into account in the draft completion.

(iii) Information for users concerning the conduction of the international search and international preliminary examination is represented on the official ROSPATENT website in the section "System of filing international applications under the Patent Cooperation Treaty (PCT)".

The said section provides information, which is classified by the following subheadings:

- the PCT News;
- Overview of the PCT;
- Practical Guide for PCT users;
- International Patent Law;
- Regulatory documents and the PCT Forms (including Russian translation of the PCT normative documents);
- Resources.

In order to provide the citizens and the institutions with the information there is a Single consulting and inquiry Service of FIPS consisting of two sections, namely of consulting section and inquiry one, which provides information on issues relating to FIPS competence.

The consulting section provides free consultations on the issues which solution does not require system analysis and/or aggregate application of the regulations of the legislation in the field of legal protection of the results of intellectual activity and means of individualization (inventions, utility models, industrial designs, trademarks and service marks, appellations of origin). The consultations are provided orally by phone, as well as at the consulting center and in writing via e-mail.

The Inquiry section is equipped with a two-channel public telephone line and provides the citizens and the institutions with the general supplemental information, including the one concerning the telephone numbers, conditions and the order of state service provision, as well as on the state of the workflow on the applications.

Another mission of the Service is the analysis and systematization of problems, as well as the selection of the most frequently asked questions and their transfer in the prescribed order to the competent experts for the preparation of a response for the publication and/or posting on the official website of ROSPATENT.

According to the work results, ROSPATENT and FIPS websites contain materials for explaining the various stages of obtaining legal protection of intellectual property for different levels of applicant preparations:

- Section “For newcomers”;
- Section “FAQ”;
- Section “*Technology and Innovation Support Centers*”, subsections “Cooperation with Russian regions”, subsection “To small and medium enterprises on the protection and use of the results of intellectual activity”.
- Section “Patent law objects”.

FIPS Consulting and Inquiry Service is equipped with an electronic data terminal for the applicants to access to the information published on the official website and intended to assist the applicants to get acquainted with the order of state service provision.

Every year conferences, seminars, topical round tables on the issues in the field of intellectual property protection are organized, that allow users to obtain information. Additionally, workshops and seminars are held at various exhibitions relating to the intellectual property in which ROSPATENT takes part, where users can also take opinion on various issues.

(iv) The Public declaration of tasks and objectives of the Federal Service for Intellectual Property for the year of ~~2017~~ 2018 is represented on the official ROSPATENT website (http://www.rupto.ru/about/opengov/publ_dec_2017.pdf). (https://rupto.ru/content/upload/files/publ_dec_2018.pdf).

In addition, users are informed of the aims and objectives in the field of quality at the annual Scientific and Practical Conferences of ROSPATENT, various seminars and round tables.

21.16 Communication with WIPO and designated and elected Offices:

Describe how the Authority provides for effective communication with the International Bureau and designated and elected offices. In particular describe how the Authority ensures that feedback is promptly evaluated and addressed.ROSPATENT and FIPS communicate with WIPO via mail, fax and email and PCT-EDI and ePCT systems.

ROSPATENT do not practically contact with designated and selected Offices via mail, fax and email on the issues related to international applications.

Since 2012 the document exchange between RO/RU and WIPO IB, and since 2014 between ISA/RU and WIPO IB has been carried out in electronic form through PCT-EDI. At that the intra-office ELA PCT system makes it possible to form in electronic form RO/RU and ISA/RU document sets that include various notifications, international search reports, written opinions, as well as requests and replacement sheets submitted by applicant, and to send the sets to WIPO IB.

Since October of 2015, ISA/RU has been using eSearchCopy service. In 2017 application copies in electronic form filed to nine receiving offices were provided for search to ISA/RU from WIPO IB via PCT-EDI system.

Since the end of 2015 IPEA/RU has been using ePCT system to download the documents related to PCT Chapter II.

Informational exchange is also carried out through the participation in the Meetings of International Authorities under the PCT. The conference participants prepare a report, which reflects the issues of greatest interest for ROSPATENT, and then an action plan to address these issues is prepared.

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 issues of the quality management are regulated by a set of documents. At present there is no single document.

Requirements with respect to the quality of the administrative procedures related to search and examination of applications are established by the Regulations.

The issues concerning the search and examination are considered in the Order of information search within substantial examination of the application for a patent for invention and a report thereon, adopted by the Order of the Ministry of economic development of the

Russian Federation № 316 as of May 25, 2016, as well as in the Guidelines for Examination of Application for inventions adopted by the Order of the Head of ROSPATENT.

The issues of classification of applications according to IPC and CPC are considered in the Guidelines for IPC Classification and JPC Manual that are updated along with the improvement of existing WIPO and EPO documents.

The procedures which are implemented within the QMS are described, in particular, in the following internal documents:

- Regulations on organization and implementation of control, analysis and evaluation of works quality in FIPS;

- Procedure for the cooperation of FIPS divisions during the performance of work related to different types of search and examination in accordance with international agreements;

- Order of organization and execution monitoring of ROSPATENT and FIPS' Heads assignments.

(See also paragraphs 21.10 (v), 21.19).

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.

(i) The Office policy in the field of quality is reflected in the ~~Development Strategy of ROSPATENT~~ *the Public Statement of goals and objectives of the Federal Service for Intellectual Property for 2018 (https://rupto.ru/content/uploadfiles/publ_dec_2018.pdf)*.

(ii) The documents mentioned in paragraph 21.18 indicate the field of application thereof.

(iii) The documents mentioned in paragraph 21.18 indicate the subdivisions entrusted with the execution of works and their competence. Besides, there is an internal document, establishing FIPS structure as well as provisions on each division forming part of the structure, which determines goals, functions, structure and rights of each division.

(iv)-(vi) The list and the description of procedures implemented by the Office in the course of carrying out the search and examination, available resources and interaction between the divisions are contained in the documents listed in paragraph 21.18.

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.

(i) FIPS has a system of technical and administrative documents storage.

(ii) See paragraph 21.08 (a).

(iii) The data relating to the professional skills of the staff and the dynamics of their promotion are stored in electronic format.

The data on the training and professional development of the staff are prepared quarterly and included in the ROSPATENT Annual Report.

(iv) The records concerning the quality of the international searches and preliminary examinations are included into the formalized conclusions which are stored in the International Patent Cooperation Division in electronic form.

(v) If the requirements for procedures and results of their fulfillment are changed (for example, due to the amendment of regulatory documents, conclusion of new international treaties, elaboration of a new practice, improvement in technical support) the internal documents are updated.

(vi) The International Search Reports, Written Opinions and International Preliminary Examination Reports are stored in the international application file for at least 10 years.

(vii) The data relating to the search carried out for particular application are stored as the search story in the internal search database (see paragraph 21.24).

(viii) On the results of the QMS inspection a reference document, conclusion or report may be issued.

(ix) (x) (xi) The decisions of Director General of ROSPATENT, Director of FIPS concerning the measures which should be taken in connection with the drawbacks revealed, are fixed in the corresponding orders or instructions of Director General of ROSPATENT or Director of FIPS.

(xii) The documenting of the search process and search results for PCT applications is made by filling the corresponding PCT form and by keeping the search history in the search database.

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.

In 2015 the Guidelines for Carrying out Information Search on inventions were amended – the list of available databases was refined and the discrepancies were eliminated. In 2016 a new edition of the Guidelines for Carrying out information search on utility models due to amendments to the Administrative Regulations adopted in 2016, was released. The Guidelines provide for the recommendations on preparing a search request and implementing the concepts (key words) used in this request into a search report. The Guidelines for Carrying out Information Search were incorporated into the Guidelines for Examination of the Patent Applications for inventions and utility models as an independent part. Search process documentation is carried out by filling in the Search Report (Form PCT/ISA/210) in accordance with the requirements and details specified by PCT International Search and Preliminary Examination Guidelines.

In the Search Report the examiners among other things indicate:

- unity / lack of unity of the invention;
- claims taken into account;
- classification of subject matter (by IPC indexes);
- search scope (by IPC indexes);
- list of used databases;
- search limitation, if:
 - claims relate to the subject matter of application which doesn't require search according to Rule 39 of the Regulations under PCT;

- claims are so unclear even taking into account the description and drawings, that it is not possible to make an comprehensive search on them;
- the requirement of unity of invention is not fulfilled and no additional fee has been paid for some claims.

Explanation for search limitation is given in the written opinion. Besides, even when search is not limited, the written opinion may include comments regarding clarity of claims, of the description and drawings and whether claims are fully supported by the description.

The recording of the search process and its results is made in PatSearch system as well as in the search systems of other providers. While using the external databases the recording of search results is made to the extent, which is provided by corresponding database.

The PatSearch system logs the search history which reflects the search sessions made by an examiner. Besides, the PatSearch system provides the compilation of statistic reports on undertaken searches which include the following data: databases used, examiner identification, a number of search requests, and a number of reviewed documents.

Due to the implementation of the search history recording software into the information retrieval system PatSearch in 2011 the unified search history form was developed. The form includes in particular the following:

- a text of the request (a combination of the search concepts and operations composing the request);
- a number of the documents cited (according to the results of this request);
- search arrays (information arrays in which the search in respect to this request has been carried out);
- the number of the documents reviewed (in respect to this request);
- a bibliography of the documents included in the final selection by the examiner.

The examiner who has carried out the search has the access to the aforementioned data (for example, for the purpose of recurrent use of obtained search results in case of similar or analogous applications). Besides, for the purposes of selective control and the solution of disputable issues, the access for these data is provided for the examiner's supervisor as well as the staff of the Quality Monitoring **Center department**.

A search history is used for the purposes of monitoring the quality of this search.

The access to search histories will be available for foreign Offices within the framework of the PPH and PCT-PPH Pilot Projects.

The PatSearch information retrieval system search history recording software permits the export of a search report in MS Word format. In 2017, PatSearch got a possibility of exporting the bibliography of the documents selected by examiners to the electronic system of internal document flow for its inclusion into the Search Report.

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.

As mentioned above in cl. 21.04, 21.06, 21.08, 21.09, 21.11 and 21.12.

9. ARRANGEMENTS FOR AUTHORITIES TO REPORT TO THE MIA

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

[End of document]