

Patent Cooperation Treaty (PCT)

Common Quality Framework for International Search and Preliminary Examination

REPORT ON QUALITY MANAGEMENT SYSTEMS

prepared by ROSPATENT

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

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

INTRODUCTION (PARAGRAPHS 21.01 - 21.03)

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

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

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

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

Abbreviations:

ROSPATENT - Federal Service for Intellectual Property FIPS - Federal State Budgetary Institution "The Federal Institute of Industrial Property", subordinate body of ROSPATENT

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

Normative reference for QMS besides Chapter 21 of the Guidelines

The issues of granting legal protection to intellectual property rights, 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 No 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 No. 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 the provision of state services) are provided by the Resolution of the Government of the Russian Federation No. 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 state services related to consideration of applications for invention (hereinafter by-law regulations) was adopted by the orders of the Ministry of Economic Development No. 315 and 316 as of May 25, 2016:

- The Administrative Regulations on the provision of state services related to registration and granting a patent for invention and a duplicate thereof by the Federal Service for Intellectual Property (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 an invention, published in the Official Bulletin of the Federal Service for Intellectual Property.
- 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.
- Eighteen standardized forms for requests and petitions that can be filed by the applicant in a proactive manner during the application process in Rospatent (annexes to the Regulations).

The aforesaid documents entered into force in August 2016.

~~The Rules and the Requirements reflect new requirements to application documents, as well as approaches on examination of industrial applicability, sufficiency of disclosure, novelty of the invention based on amendments to the Civil Code.~~

~~The Administrative Regulations were amended in 2016 and 2017; the Rules were amended in 2018, aimed at preventing the practice of “double” patenting of already known pharmaceutical compositions and use thereof. According to the changes introduced, for characterizing a composition it is not allowed to use as its features the data not directly associated with the composition (for example, the conditions and modes of use of this composition in any process, method), quantitative (measured or calculated) parameter characterizing one or more properties of the composition, in cases where this parameter is a distinctive feature in the characteristics of the composition in an independent claim (for example, parameters of lamination strength, stress cracking resistance, pharmacokinetic profile, and the like), the technical result that develops during the production or use of the composition. When characterizing a pharmaceutical composition, the use of features related to a method of treating or preventing a disease (for example, an indication of doses, conditions or modes of use of the composition or medical preparations achieved on its basis) is not allowed.~~

~~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.

In 2020, the Civil Code was amended by the Federal Law No. 217-FZ «On amendments to Part Four of the Civil Code of the Russian Federation» of July 20, 2020 (the Federal Law No. 217-FZ). The Law introduced for the first time a new part of the application — a three-dimensional representation of an invention or utility model in an electronic format. Applicants may use an electronic format to describe the claimed invention or utility model in their applications. The Federal Law provides for the granting of a patent for an invention and utility model in the form of an electronic document. A traditional paper format of patents ~~will~~ **may** be issued at the applicants' request. **The changes made are aimed at expanding the list of submitted application documents, thus allowing to disclose more exhaustively the substance of claimed solution and automate the procedure of conducting information search on the application, as well as improving the procedure of granting a patent using modern technologies.**

The Federal Law N 217-FZ **entered** into force on January 17, 2021.

The Federal Law N262-FZ «On Amendments to Part Four of the Civil Code of the Russian Federation» of July 31, 2020, (hereinafter referred to as Federal Law N 262-FZ) introduced a new additional procedure in the registration of an invention and utility model and the granting of a patent for an invention and utility model, and modification and supplementation of several existing procedures, including carrying out searches at the applicant's request, the substantial examination, publication of information about the application and granting of the patent amendments to the application documents and other changes.

The new procedure **is will be** carried out upon the applicant's request and consists of preliminary information search and preliminary assessment of the patentability of the claimed invention or utility model by Russian scientific and educational organizations accredited by Rospatent as organizations that can carry out such search and assessment. The Federal Law specifies that Rospatent's examiners should take into account the results of the preliminary information search and preliminary patentability assessment when they are examining the patent applications for inventions and utility models. **Using the results of the examination conducted by specialized experts engaged in scientific work will allow increasing the quality of granted patents.**

The changes to the procedures ~~will take effect~~ **took effect** on August 1, 2021.

For the implementation of the procedures provided by Federal Law No. 262-FZ the following documents were approved:

- Decree of the Government of the Russian Federation No. 1202 of July 15, 2021 "On Approval of the regulations on the accreditation by the federal executive authority on the intellectual property of a Russian scientific or educational organization acting as the organization that can conduct the preliminary information search concerning the claimed inventions or utility models and preliminary assessment of their patentability, and on amending the list of services that are necessary and obligatory for the provision of state services by federal executive authorities, "Rosatom State Nuclear Energy Corporation", and are provided by the organizations involved in the provision of state services"; enters into force on March 1, 2022, except for clause 2 which enters into force on August 1, 2021;

- Order of the Ministry of Economic Development of the Russian Federation No. 295 of May 26, 2021 "On Approval of the procedure for conducting a preliminary information search concerning the claimed invention and preliminary assessment of patentability thereof, submission of a report on the preliminary information search and an opinion on the results of a preliminary assessment of patentability in respect of the claimed invention, publication of the preliminary information search report in relation to the claimed invention ", entered into force on September 20, 2021.

Due to the ongoing administrative reform in the Russian Federation, the Order of Rospatent No. 163 of December 11, 2020, approved the Administrative Regulations (effective date - June 19,

2021), taking into account, as well, the changes introduced to the Code by the Federal Law No. 217-FZ, Federal Law No. 262-FZ. At the same time, the Administrative Regulations approved by the order of the Ministry of Economic Development of the Russian Federation No. 315 of May 25, 2016, lapsed.

The purpose of regulation within the framework of the Administrative Regulations is to ensure the optimization of procedures for obtaining a patent, a clear regulation of the sequence and timing of administrative actions.

The handling of objections to Rospatent's 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 N 210-FZ as of July 27, 2010 "On the 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 N 840 as of August 16, 2012 (as amended).

The processing of the requests of the applicants, right holders and other persons on other issues related to the activities of ROSPATENT, are regulated by the Federal Law N 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 2020 2021 (<https://rospatent.gov.ru/content/uploadfiles/publ-dec-2020.pdf>) (<https://rospatent.gov.ru/content/uploadfiles/publ-dec-2021.pdf>). The Head 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 Ms. ~~Liubov KIRIY~~, Ms. Viktoria Galkovskaya, Deputy Head 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. Dmitriy TRAVNIKOV, Director of the Department for the Provision of State Services of ROSPATENT.

2) In 2018, structural and personnel changes took place in FIPS, subordinate body of 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.

In 2019, the division for monitoring processes and results of provision of public services and ISO certification was transformed into two units - the sector for monitoring processes and results of provision of public services and the ISO certification sector. The ISO certification sector is not part of the Quality Monitoring Center and reports directly to the FIPS Director. In 2019, FIPS was headed by Mr. Oleg NERETIN.

In 2020, the sector for monitoring processes and results of the provision of public services was abolished. The ISO certification sector has been transformed into International Certification Centre.

The International Certification Centre manages the following issues:

- coordination of work on developing, implementing and improving the QMS in FIPS based on the requirements of international standards;
- preparation and organization of internal audits of the QMS according to the requirements of international standards with the direct participation of directors of associated structural subdivisions of FIPS;
- organization of certified audits of the QMS, including compliance audit, by the certification authorities;
- organization of training for employees of FIPS in the field of quality management using international standards.

The structure, tasks, functions, responsibilities and interaction with other FIPS and Rospatent units are specified by an internal document — Regulation on the Quality Monitoring Centre, approved by the Order of FIPS Director № 480 of November 11, 2020.

The management of the Center is assigned to Ms. Natalia Chikanova, Head of the Center.

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

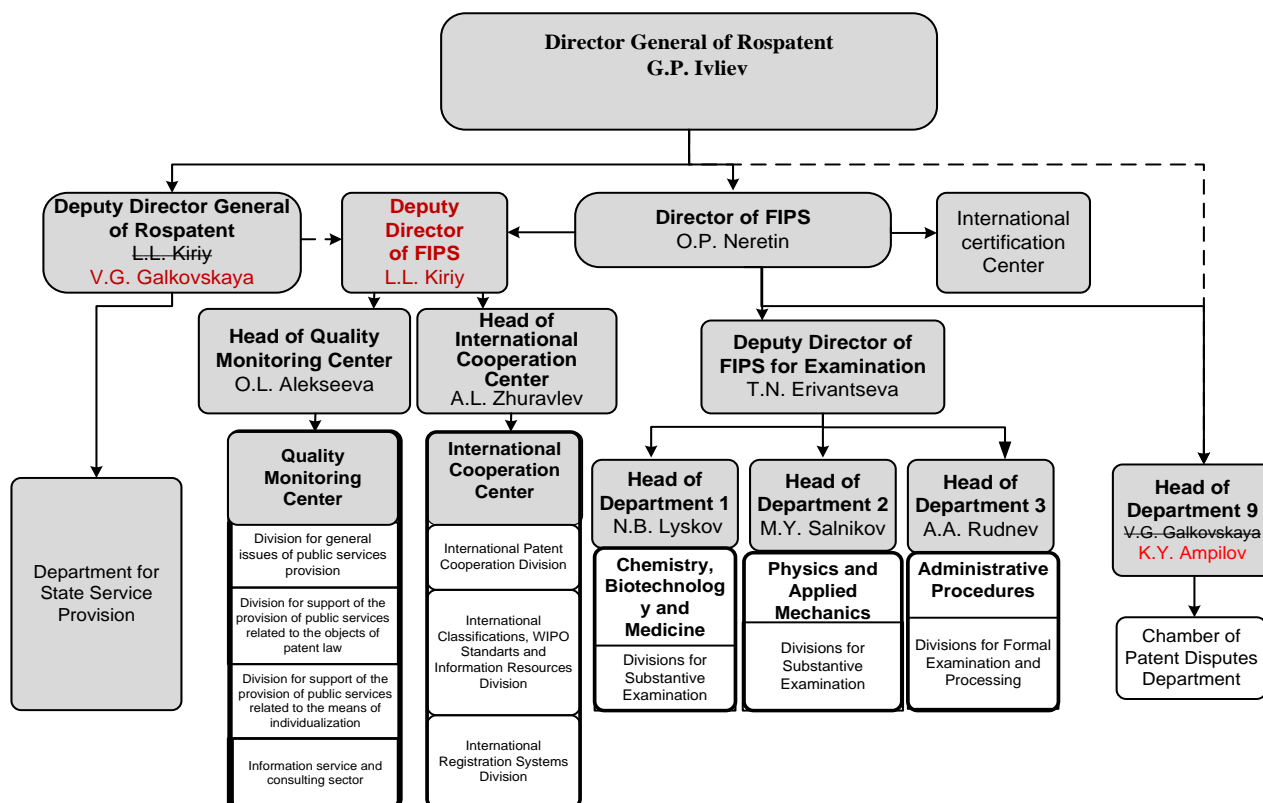
- providing systematic, including operational, and methodical support to examination divisions;
- monitoring the quality of public services, in particular, monitoring:
 - functioning of the quality management system,
 - actions and documents prepared by the examiners and other FIPS employees in the implementation 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 structure, tasks, functions, responsibilities and cooperation manner with other FIPS and Rospatent units are specified by a departmental document — Regulation on the Quality Monitoring Centre, approved by the Order of FIPS Director № 297 dated July 6, 2020.

The management of the Center is assigned to Ms. Olga ALEKSEEVA, 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 ~~Ms. Liubov KIRIY~~ Ms. Viktoria Galkovskaya, Deputy Head of ROSPATENT, and by FIPS Director.

4) International Patent Cooperation Division dealing with quality check of the international search reports, written opinions and international preliminary examination reports. The Division is headed by Ms. Liubov SENCHIKHINA. The Division is the part of the International Cooperation Center, established in 2018. The management of the International Cooperation Center is assigned to Mr. Andrey ZHURAVLEV, 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. Grigory Ivliev, Head of ROSPATENT.

The ROSPATENT Quality Council was established in 2016. The Quality Council consists of all leading specialists of ROSPATENT and FIPS, subordinated body 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 (https://rospatent.gov.ru/ru/about/consult/sovet_po_kachestvu) available for the open access.

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

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

Chapter 21 requirement				Extent of compliance		
				full	Part.	no
21.04		(a)	Quality policy available	✓		
		(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 to the relevant staff at the Authority	✓		
21.09		(a)	Performance of a yearly internal review of the QMS in/to	✓		
		(b)	determine the extent to which the QMS is aligned with Chapter 21; determine the extent to which S&E complies with PCT Guidelines	✓		
		(c)	an objective and transparent way	✓		
		(d)	using input incl. information according paragraph 21.29	✓		
		(e)	recording the results	✓		
21.10			Risk and opportunities are addressed that can affect the QMS and the conformity of search and examination	✓		
21.13			Arrangements for establishing risk-based practices to	✓		
	(i)	(a)	understand issues that affect its ability to achieve intended results of the QMS	✓		
		(b)	understand the needs and expectations of interested parties	✓		
	(ii)		identify risks and opportunities related to the performance of the QMS as a basis for planning	✓		
	(iii)		plan and implement actions to address risks and opportunities	✓		
	(iv)		check the effectiveness of the actions taken	✓		

Chapter 21 requirement			Extent of compliance		
			full	Part.	no
	(v)	continuously update risks and opportunities.	✓		
21.15		Assurance to monitor and adapt to actual workload	✓		
	(i)	Infrastructure in place to ensure that a quantity of staff	✓		
	(a)	sufficient to deal with the inflow of work	✓		
	(b)	which maintains technical qualifications to S&E in all technical fields	✓		
	(c)	which maintains the language facilities to understand languages according to Rule 34	✓		
	(ii)	Infrastructure to provide a quantity of skilled administrative staff	✓		
	(a)	at a level to support the technically qualified staff	✓		
	(b)	for the documentation of records	✓		
	(iii)	Ensuring appropriate equipment to carry out S&E	✓		
	(iv)	Ensuring documentation according to Rule 34	✓		
	(v)	(a) Instructions to help staff understand and act according to the quality criteria and standards	✓		
		(b) Instructions to follow work procedures accurately and they are kept up-to-date.	✓		
	(vi)	(a) Training and development program to ensure and maintain necessary skills in search and examination	✓		
		(b) Training and development program to ensure awareness of staff to comply with the quality criteria and standards.	✓		
	(vii)	(a) System in place for monitoring resources required to deal with demand	✓		
		(b) System in place for monitoring resources required to comply with the quality standards in S&E	✓		
21.16	(i)	Control mechanisms to ensure timely issue of S&E reports	✓		
	(ii)	Control mech. regarding fluctuations in demand and backlog	✓		
21.17	(i)	Internal quality assurance system for self-assessment	✓		
		(a) for compliance with S&E Guidelines	✓		
		(b) for channeling feedback to staff	✓		
	(ii)	System for measurement of data and reporting for continuous improvement	✓		
	(iii)	System for verifying the effectiveness of actions taken to correct deficient S&E work, eliminate the causes and prevent issues from recurring	✓		
21.19		(a) Contact person helping identify best practice between Authorities	✓		
		(b) Contact person fostering continual improvement	✓		
		(c) Contact person providing for effective communication with other Authorities for feedback and evaluation	✓		
21.20	(i)	(a) Appropriate system for handling complaints	✓		

Chapter 21 requirement			Extent of compliance		
			full	Part.	no
	(b)	Appropriate system for taking preventive/corrective actions	✓		
	(c)	Appropriate system for offering feedback to users	✓		
(ii)	(a)	A procedure for monitoring user satisfaction & perception	✓		
	(b)	A procedure for ensuring their legitimate needs and expectations are met	✓		
(iii)		Clear and concise guidance on the S&E process for the user	✓		
		Indication where and how the Authority makes its quality objectives publicly available	✓		
21.21		Established communication with WIPO and designated and elected Offices	✓		
21.22		QMS of Authority clearly described and documented (for e.g. Quality Guidelines)	✓		
21.23	(a)	Material making up the reference of quality procedures and processes for staff and management has been prepared and distributed	✓		
	(b)	Media available to support the reference material for Quality Guidelines	✓		
	(c)	Document control measures are taken	✓		
21.24	(i)	Quality policy of the Authority and commitment to QMS	✓		
	(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.	✓		
21.25	(i)	Records which documents are kept and where they are kept	✓		
	(ii)	Records of results of management review	✓		
	(iii)	Records about training, skills and experience of staff	✓		
	(iv)	Evidence of conformity of processes	✓		
	(v)	Results of reviews of requirements relating to products	✓		
	(vi)	Records of the S&E process carried out on each application	✓		
	(vii)	Record of data allowing individual work to be tracked	✓		
	(viii)	Record of QMS audits	✓		
	(ix)	Records on actions taken re. non-conforming products	✓		
	(x)	Records on actions taken re. corrective actions	✓		
	(xi)	Records on actions taken re. preventive actions	✓		
	(xii)	Records referring to search process documentation	✓		
21.26	(i)	Recording of the databases consulted during search	✓		

Chapter 21 requirement			Extent of compliance		
			full	Part.	no
	(ii)	Recording of keywords, combination of words and truncations during search	✓		
	(iii)	Recording of the languages used during search	✓		
	(iv)	Recording of classes and combinations thereof consulted during search	✓		
	(v)	Recording of a listing of all search statements used in databases consulted		✓	
	(vi)	Records about other information relevant to the search	✓		
	(vii)	Records about limitation of search and its justification	✓		
	(viii)	Records about lack of clarity of the claims	✓		
	(ix)	Records about lack of unity	✓		
21.27		Report on its own internal review processes	✓		
21.28-21.30		Additional information on further inputs to its internal reviews		✓	
21.31		Initial report called for by paragraph 21.31	✓		

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

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

(a), (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 Head 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.

In 2020, the International Certification Centre became responsible for coordinating the development, implementation, and improvement of the QMS, taking into account the requirements of international standards.

In 2021, a work began on certification of international search and international preliminary examination processes under the Patent Cooperation Treaty (PCT) in accordance with the requirements of ISO 9001-2015 (see clause 21.10).

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 Head 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 Head 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.

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 Head 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 of FIPS, International Patent Cooperation Division, heads of examination departments.

Reports prepared according to the results of inspections are presented to the Head 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 21.27-21.30:

- (a) at least once per year (cf. paragraph 21.27);*
- (b) in accordance with the minimum scope of such reviews as set out in Section 8, namely: to determine the extent to which the QMS is based on Chapter 21 (cf. paragraphs 21.27, 21.29(i)); to determine the extent to which Search and Examination work complies with PCT Guidelines (cf. paragraphs 21.27, 21.29(i));*
- (c) in an objective and transparent way (cf. paragraph 21.27);*
- (d) using input including information according to paragraphs 21.29 (ii)-(vi);*
- (e) recording the results (cf. paragraph 21.30).*

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 Head 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.

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

Rospatent's management encourages the practice of ensuring that risks and opportunities that may affect its Quality Management System (QMS) and compliance with requirements are taken into account.

~~In 2020, Rospatent plans to carry out work related to the preparation for certification of a number of activities in accordance with the requirements of the international standard ISO 9001-2015, in particular, the processes of international search and international preliminary examination under the Patent Cooperation Treaty (PCT).~~

~~In 2021, a work began on certification of international search and international preliminary examination processes under the Patent Cooperation Treaty (PCT) in accordance with the requirements of ISO 9001-2015.~~

~~In accordance with the requirements of ISO 9001-2015, the following documents were approved:~~

- ~~- Policy in the field of quality (order No. 184 of 05.05.2021);~~
- ~~- Quality Guidelines for International Search and International Preliminary Examination Processes under the Patent Cooperation Treaty (Order No. 501 of November 26, 2021);~~

- Procedure for internal audit in relation to the processes of international search and international preliminary examination under the Patent Cooperation Treaty (Order No. 501 of November 26, 2021);

- Procedure for QMS Analysis by FIPS management in relation to the processes of international search and international preliminary examination under the Patent Cooperation Treaty (Order No. 501 of November 26, 2021);

- Objectives in the field of quality in the area of activity of the Center for International Cooperation (order No. 501 of November 26, 2021).

In December 2021, internal audits of the main and supporting processes of international search and international preliminary examination under the Patent Cooperation Treaty were carried out. In 2022, it is planned to submit an application for an audit by a competent authority for compliance of QMS as applied to the processes of international search and international preliminary examination under the Patent Cooperation Treaty with the requirements of ISO 9001-2015.

2. RISK-BASED PRACTICES

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

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

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

21.13 Arrangements for establishing risk-based practices

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

- (i) (a) understand issues that affect its ability to achieve intended results of the QMS, and (b) understand the needs and expectations of interested parties;*
- (ii) identify risks and opportunities related to the performance of the QMS as basis for planning;*
- (iii) plan and implement actions to address risks and opportunities;*
- (iv) check the effectiveness of the actions taken; and*
- (v) continuously update risks and opportunities.*

21.14 Explanatory note: All processes of the QMS present differing levels of risk in terms of the Authority's ability to meet its objectives, and the effects of uncertainty are not the same for all Authorities. Each Authority is responsible for the actions it decides to take to address risks and opportunities.

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

The process of assessing and monitoring risks and opportunities is organized in the following manner:

-registering complaints of the applicants concerning the quality of provided State services — granting of patents for inventions and utility models — in particular, the completeness and quality of searches and the examination of applications;

- carrying out routine quality control of the searches and documents sent to the applicant, routine and random checks of completeness and quality of the State services related to the issuance of patents for inventions and utility models;
- analyzing the causes of violations, regulatory gaps, and methodological problems identified through the examination of complaints and checks, as well as the development of measures to prevent these risks;
- registering and analyzing comments and suggestions of Rospatent staff and developing measures to improve the patent search and examination process;
- monitoring FIPS' activity performance;
- implementing activities included in the Rospatent and FIPS annual and long-term activity plans aimed at improving the quality of search and examination of applications for inventions, optimization of the processing technique, and use of new information technologies.

3. RESOURCES

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

Human resources:

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

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

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

is maintained and adapted to changes in workload.

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

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

for the documentation of records.

(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 12.0) 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 ~~2020~~ 2021, the following measures were taken with regard to staff:

- due to ~~the threat of~~ the spread of coronavirus infection (2019-nCoV), more than 40% of Rospatent and FIPS employees were switched to remote work mode;

- continued work on improving the remuneration of labor and bonuses to employees of the examining divisions;

- in order to implement the Russian Federation 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 to perform patent examination;

- in order to enhance FIPS staff skills, a contract with RGAIS was concluded to provide education in the field of intellectual property; moreover, the staff members are regularly participating in WIPO training activities;

- ~~The Novosibirsk division of FIPS was transformed into the Siberian Center of FIPS with the addition of functions for examination of trademark applications. The specialists were trained under the program "Raising the Qualification of Experts in Examination of Trademark Applications". There are 49 specialists working at the Siberian Center of FIPS, 37 of them are experts (the Trademark Applications Examination Department has 20 experts, the Utility Models Department has 17 experts).~~

Concerning staffing levels, it should be noted that in ~~2020~~ 2021 the total number of examiners ~~was increased from~~ 818 to 870, of whom ~~492~~ 502 examiners were engaged in international search and international preliminary examination and related work.

The work related to the international search and preliminary examination is overseen and the quality of reports is checked by examiners of the International Patent Cooperation Division (number of staff is ~~34~~ 30, 12 of them are dealing with international search and preliminary examination, as well as quality control thereof).

(ii) There is a sufficient number of personnel for the 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:

- Department for design, development and operation of applied information systems dealing with 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' workstations 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. 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 intra-office PatSearch retrieval system also includes a collection of Derwent World Patent Index (DWPI) database by Clarivate Analytics and, since 2020, a collection of English-language texts of patent documents by LexisNexis.

The examiners have online access via Internet to updating search resources, including web-sites of the foreign patent offices (WIPO, EPO, the USA, Japan, the Republic of Korea, China, Germany, and others).

The sites containing non-patent information, relating to medicine, pharmaceuticals, chemistry, and biotechnology (for example, 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 freely accessible databases, in ~~2020~~ 2021, the examiners had access to commercial databases: STN International, Reaxys® - Life Science IP Ltd, ~~Global Patent Index (GPI), Derwent World Patent Index (DWPI), SAEGIS, SCOPUS, Science Direct,~~ Orbit Intelligence, ~~Web of Science, Reaxys и Embase, as well as Electronic library of dissertations of the Russian State Library (RSL).~~ Inter alia, in ~~2020~~ 2021 within the scope of the “National Subscription” Project, FIPS got free access to ~~4 5~~ commercial databases (SCOPUS, Science Direct, Web of Science, ~~Freedom Collection of Elsevier publishing office, QUESTEL – ORBIT), to SPRINGER NATURE's electronic resources and to the content of Wiley journals. Additionally, since September 2019 within the scope of the “National Subscription” Project, FIPS has access to the Russian Science Citation Index (RSCI) database on the Web of Science platform.~~

Since October 2017, full access to the Kluwer IP Law electronic resource (<http://kluweriplaw.com/>) on international legislation in the field of intellectual property by Wolters Kluwer - Kluwer Law International B.V, has been provided.

In ~~2020~~ 2021, the examiners have access from their workstations to 26 periodicals of scientific, technical, and patent-related legal topics subscribed in electronic form, as well as to protected content of the National Electronic Library, ~~including the Electronic Library of Dissertations of the Russian State Library (RGB).~~

Trained patent searchers assist patent examiners in carrying out searches in the specified commercial search systems.

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 copies of 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 exercising administrative procedures and actions in the framework of the provision of public service on state registration of invention and grant of a patent for invention, a duplicate thereof are used, which were developed in 2018 to provide methodological support for the processing of applications. While developing these Guidelines, the Guidelines for Examination of Applications for Inventions adopted by order of ROSPATENT in 2011 and updated in 2013 and 2014, were used in the course of which development the EPO Examination Guidelines and the PCT International Search and Preliminary Examination Guidelines were used.

All of the mentioned Guidelines, as well as the list of Internet sites to which experts are allowed to access from their automated workstations, are posted on the public segment of the intradepartmental computer network.

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 FIPS Director 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 examiners 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 higher education in the fields of “Jurisprudence” and “Management”.

5.2 Post-graduate course in RGAIS.

6. The following training programs, developed by FIPS’ specialists and targeting beginner examiners, are indivisibly linked to the working process:

- Advanced Training for Examiners Working on Applications for Inventions and Utility Models» (232 academic hours);
- Advanced Training for Examiners Working on Trademark Examination» (130 academic hours).

In addition to the lectures presenting theoretical materials, practical exercises and business games are organized in small groups based on studying examiners' requests. Highly qualified FIPS’ examiners (practicing trainers) are involved in the training. Teaching materials are developed by practicing trainers based on real issues arising in examiners' work. During the training (3-4 months), in addition to the main theoretical part, an examiner examines real applications, which helps him/her acquire professional skills already at the education stage. In 2021, more than 100 beginner examiners passed these programs, including in the dynamically developing division of FIPS - the Siberian Center of FIPS (Novosibirsk).

In 2021 experienced examiners go on participating in free advanced distance training programs entitled Introduction to Technology Transfer, Establishment of Regional Brands, Recommendations on the Management of the Rights on Results of Intellectual Activity and Means of Individualization in Regions of the Russian Federation, Commercial and Regulatory Specificity of Circulation of Medicines in the Context Terms of IP Rights Protection. ~~In 2020, more than 100 beginner examiners passed these programs.~~

In 2021, as part of the measures to develop and introduce a quality management system that meets the requirements of ISO 9001:2015 in FIPS, two educational seminars were organized for the management and expert departments of FIPS under the professional development program "International Standard ISO 9001:2015. QMS and Audits". 55 employees of FIPS were trained under this program.

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 access from workstations (in case of free access), or in special Search Rooms (in case of non-free access). The reclassification of national documents is carried out within the process of revision of the International Patent Classification.

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).

4. MANAGEMENT OF ADMINISTRATIVE WORKLOAD

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

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

The International Patent Cooperation Division (IPCD):

- records applications received for international search and international preliminary examination, prepares notifications of their receipt;
- prepares an assignment to appropriate examining division with indication of deadline for submission of reports to the IPCD;
- collects from examining divisions and checks the international search reports or declarations of on-establishment of international search report, ISA and IPEA written opinions and the international preliminary examination reports (reporting documents), prepares sets of notifications and reporting documents to be sent;
- transmits the notifications and reporting documents to the International Bureau 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.

5. QUALITY ASSURANCE

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

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

for compliance with these Search and Examination Guidelines;

for channeling feedback to staff.

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

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

(i) The following quality assurance scheme of drawing up international search and preliminary examination reports is provided in the Office, **which is consistent with the approved Quality Management System (QMS) documents for international search and international preliminary examination processes under the PCT (see paragraph 21.10).**

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. When the head of examining division disagrees with the IPCD opinion, 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 the PCT and the PCT International Search and Preliminary Examination Guidelines, **and also taking into account the approved Quality Management System (QMS) documents related to the international search and international preliminary examination processes under the PCT (see paragraph 21.10).** 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.

Monthly the IPCD 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.

6. COMMUNICATION

Inter-Authority communication:

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

(Note: This point is informative. No response is required by the template to paragraph 21.18)

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

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

(a), (b), (c) Ms. Margarita AGARKOVA, Deputy Head, International Patent Cooperation Division, email: amv20otd@rupto.ru

Ms. Elena SOROKINA, Deputy Head, Quality Monitoring Center; Head, Division for General Issues of Public Services Provision, e-mail: otd18ch@rupto.ru

Communication and guidance to users:

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

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

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

(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);
- Rules for filing and considering complaints against decisions and actions (inaction) of the federal executive bodies and the officials thereof, federal public officers, the officials of state off-budget funds of the Russian Federation, approved by the Decree of the Government of the Russian Federation No. 840 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, Rospatent № 163 as of December 11, 2020~~, registered with the Ministry of Justice of the Russian Federation ~~as of July 14, 2016 (as amended)~~ as of February 15, 2021;
- 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.

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

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, a position 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~~ **The position of the Quality monitoring Center** 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 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 Head 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 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:

- 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 examiners 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 «Inventions and Utility Models».

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 ~~2020~~ 2021 is represented on the official ROSPATENT website (<https://rospatent.gov.ru/content/uploadfiles/publ-dec-2020.pdf>) (<https://rospatent.gov.ru/content/uploadfiles/publ-dec-2021.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.

21.21 Communication with WIPO and designated and elected Offices:

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

ROSPATENT communicates with WIPO via email and PCT-EDI and ePCT systems.

ROSPATENT does 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 the International Bureau, since 2014 between ISA/RU and the International Bureau has been carried out in electronic form through PCT-EDI. 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 the International Bureau.

Since October of 2015, ISA/RU has been using eSearchCopy service. In ~~2020~~ 2021 application copies in electronic form filed to thirteen receiving offices were provided for search to ISA/RU from the International Bureau via PCT-EDI system.

Since 2015 IPEA/RU and SISA/RU have been receiving the Demands and Supplementary search requests from the International Bureau via PCT-EDI. 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.

7. DOCUMENTATION

21.22 Explanatory note: The QMS of the Authority needs to be clearly described and implemented so that all processes in the Authority and the resulting products and services can be monitored, controlled, and checked for conformity. This is done in the documents that make up the Quality Manual of the Authority (see paragraph 21.23).

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

21.23 The 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 No. 316 as of May 25, 2016, as well as in the Guidelines for exercising administrative procedures and actions in the framework of the provision of public service on state registration of inventions and grant of a patent for invention.

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.~~

~~- Procedure for executing by FIPS divisions the work related to performing by Rospatent the functions of the International Searching Authority and the International Preliminary Examining Authority under the Patent Cooperation Treaty;~~

~~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;~~

(See also paragraphs 21.15 (v), 21.24).

~~- Quality Guidelines for International Search and International Preliminary Examination processes under the Patent Cooperation Treaty;~~

~~- Internal Audit Procedure for International Search and International Preliminary Examination processes under the Patent Cooperation Treaty;~~

~~- Procedure for QMS analysis by FIPS management in relation to the processes of International Search and International Preliminary Examination under the Patent Cooperation Treaty.~~

21.24 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 Public Statement of goals and objectives of the Federal Service for Intellectual Property for 2020 2021 (<https://rospatent.gov.ru/content/uploadfiles/publ-dec-2020.pdf>) (<https://rospatent.gov.ru/content/uploadfiles/publ-dec-2021.pdf>).

(ii) The documents mentioned in paragraph 21.23 indicate the field of application thereof.

(iii) The documents mentioned in paragraph 21.23 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 21.23.

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

- (i) a definition of which documents are kept and where they are kept;*
- (ii) results of management review;*
- (iii) training, skills and experience of personnel;*
- (iv) evidence of conformity of processes, resulting products and services in terms of quality standards;*
- (v) results of reviews of requirements relating to products;*
- (vi) the search and examination processes carried out on each application;*
- (vii) data allowing individual work to be tracked and traced;*
- (viii) records of QMS audits;*
- (ix) actions taken re. non-conforming products, e.g. examples of corrections;*
- (x) actions taken re. corrective action;*
- (xi) actions taken re. preventative action; and*
- (xii) search process documentation as set out in Section 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 21.26).

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

(ix) (x) (xi) The decisions of the Head 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 the Head of ROSPATENT or Director of FIPS.

(xii) Documentation of the search process carried out on the PCT applications is done by keeping the search history in the search database, the search results are entered into the PCT form used for the compilation of the international search report.

8. SEARCH PROCESS DOCUMENTATION

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

The Authority should indicate

(a) which of the following are included in this record:

- (i) the databases consulted (patent and non patent literature);
- (ii) the keywords, combinations of words and truncations used;
- (iii) the language(s) in which the search was carried out;
- (iv) the classes and class combinations searched, at least according to the IPC or equivalent;
- (v) a listing of all search statements used in the databases consulted.

(b) which other information relevant to the search itself is included in this record e.g. a statement of the subject of search; details of special relevance to internet searching; a record of documents viewed; on-line thesaurus, synonym or concept databases, etc.

(Explanatory note: The IA is requested to list other information it may collect to monitor and improve the search process)

(c) which special cases are documented and whether records are kept denoting any:

- (vi) limitation of search and its justification
- (vii) lack of clarity of the claims; and
- (viii) lack of unity.

The search procedure is regulated by the following documents:

- The Rules of compilation, filing and consideration of documents being the basis for exercising legally significant actions on state registration of inventions, and the forms thereof (similar Rules have been released for utility models);
- The order of information search in the course of substantive examination of application for grant of a patent for invention and providing a report thereon;
- The order and time limits for informing an applicant on the results of information search on application for grant of a patent for invention and publication of such search report;
- ~~The order and conditions of information search on application for grant of a patent for invention at the request of the applicant or third persons and providing data on the results thereof;~~
- ~~The order for preliminary information search in relation to the claimed invention and preliminary assessment of patentability thereof, submission of a preliminary information search report and opinion based on the results of preliminary assessment of patentability in relation to the claimed invention, publication of a preliminary information search report in relation to the claimed invention. The order has been developed due to the changes to the Code introduced by the Federal Law No. 262-FZ. The preliminary information search and preliminary assessment of patentability are performed upon the initiative of the applicant. The results of the preliminary information search and the preliminary assessment of patentability are taken into account when making a decision based on the results of the substantive examination.~~

~~The steps of the search procedure are disclosed in more detail in the guideline documents issued in 2018, namely, in section VII of the Guidelines for exercising administrative procedures and actions in the framework of the provision of public service for state registration of invention and grant of a patent for invention, a duplicate thereof, and section V of the similar Guidelines for utility Models.~~

The Guidelines for executing administrative procedures and actions within the framework of the provision of state service on state registration of an invention and grant of a patent for invention, a duplicate thereof and the Guidelines for executing administrative procedures and actions within the framework of the provision of state service on state registration of a utility model and grant of a patent for utility model, a duplicate thereof, contain detailed explanations for conducting an information search.

Said Guidelines provide for the recommendations on preparing a search request and implementing the concepts (key words) used in this request into a search report.

In order to ensure quality control of searches, examiners have been required to document the search process since 2011, in accordance with the Instructions for preparing the search history and the resulting document set (Internal orders N 159/16 dated June 1, 2011, and N 195/16 dated June 30, 2011).

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.

The unified search history form includes 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 to the management staff as well as the staff of the Quality Monitoring Center.

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. Since 2017, PatSearch provides the ability 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.

Search results are documented 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 addition to assessing novelty and inventive level, an examiner indicates the following in the International Search Report:

- non-conformity with the unity requirement;
- classification of subject matter (IPC indexes);
- field of search (IPC indexes);
- list of used databases;
- search limitation, if:
 - certain claims relate to the subject matter which doesn't require international search according to Rule 39 of the Regulations under PCT;
 - certain claims are so unclear even taking into account the description and drawings, that it is not possible to make a comprehensive search on them;
 - the requirement of unity of invention is not fulfilled and no fee has been paid for certain claims.

In addition to giving an opinion as to whether the claimed invention is new, inventive and industrially applicable, the written opinion provides a substantiated explanation of the reasons for the search limitations. Besides, the written opinion may include notes regarding clarity of claims, of the description and drawings and whether the claims are fully supported by the description.

9. INTERNAL REVIEW

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

21.28-21.30 These arrangements are reported according to this template in Section 1, above, at points 21.04 - 21.09. The Authority may provide additional information on further inputs to its internal reviews under this section, if it so wishes.

As mentioned above in cl. 21.04, 21.06, 21.08, 21.09, 21.16 and 21.17

10. ARRANGEMENTS FOR AUTHORITIES TO REPORT TO THE MIA

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