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WIPO
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INTELLECTUAL PROPERTY
ORGANIZATION

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Patent Cooperation Treaty (PCT)

Common Quality Framework for International Search and Preliminary Examination

INITIAL REPORT ON QUALITY MANAGEMENT SYSTEMS

prepared by 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.

Used abbreviations:

Rospatent – Federal Service for Intellectual Property

FIPS – Federal State Budgetary Institution “The Federal Institute of Industrial Property”, subordinate body of Rospatent

RSAIP – 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 (the Code), which was put into force by the Federal Law No. 230-FZ as of December 18, 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 amendments made to Part IV of the Code, aimed, *inter alia*, at improving the quality of patents and legal protection reliability, as well as at harmonizing the material and procedural rules governing the protection of inventions with the international standards.

The functions of the federal executive body for intellectual property in the Russian Federation 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. The Ministry of Economic Development of the Russian Federation is a federal executive body that carries out legal regulation in the field of intellectual property. The Ministry of Economic Development of the Russian Federation, in particular, approves by-laws that establish, in particular, the Requirements for application documents for a patent for invention, utility model, the rules for preparation, filing and consideration thereof.

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 a new part of the application: a three-dimensional (3D) 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 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 No. 217-FZ entered into force on January 17, 2021.

The Federal Law No. 262-FZ “On Amendments to Part Four of the Civil Code of the Russian Federation of July 31, 2020, (hereinafter referred to as Federal Law No. 262-FZ) introduced a new procedure in the registration of an invention and utility model and the granting of a patent for an invention and utility model, providing for a preliminary information search and a preliminary assessment of patentability in relation to the claimed invention, utility model by Russian scientific and educational organizations accredited by Rospatent. The new procedure is optional and is carried out at the initiative of the applicant. At that, the Code provides for taking into account the results of a preliminary information search and a preliminary assessment of patentability when considering applications for a patent for an invention and applications for a patent for a utility model in Rospatent. The use of the results of consideration of the application by subject matter specialists engaged in scientific activities during the examination of the application will improve the quality of granted patents.

In addition, Federal Law No. 262-FZ introduced amendments regarding, in particular, the possibility of amending the documents of an application for an invention or utility model after receiving a report on a preliminary information search, when submitting a request for substantive examination of an application for an invention; the opening date for the term for filing a request for substantive examination of an application for an invention for international applications entered to the national phase of examination by Rospatent has been specified.

The changes to the procedures on August 1, 2021.

For the purposes of implementation of the procedures provided by the 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 intellectual property of a Russian scientific or educational organization acting as the organization that can conduct the preliminary information search in relation to 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"; entered into force on March 1, 2022, except for clause 2 that entered 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 in relation to a 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 (Procedure 1);
- Order of the Ministry of Economic Development of the Russian Federation No. 321 of June 22, 2022 “On approval of the procedure for conducting a preliminary information search in respect of the claimed utility model and preliminary assessment of patentability thereof, submitting a preliminary information search report and a report on the results of a preliminary assessment of patentability in respect of the claimed utility model”, entered into force on October 3, 2022 (Procedure 2);

- As of December ~~2023~~ 2024, under implementation of the procedures provided for by the Federal Law No. 262-FZ, Rospatent accredited ~~7~~ 8 educational organizations of higher education and scientific institutions as organizations that can conduct preliminary information search in relation to claimed inventions or utility models and preliminary assessment of the patentability, after representatives of these organizations have passed the relevant exams at the FIPS.

Under the ongoing administrative reform taking place in the Russian Federation, the Order of Rospatent No. 163 of December 11, 2020, approved the Administrative Regulations (effective from June 19, 2021), taking into account, as well, the changes introduced to the Code by the Federal Law No. 217-FZ and the Federal Law No. 262-FZ. The Administrative Regulations replaced the previous Administrative Regulations approved by the Order of the Ministry of Economic Development of the Russian Federation No. 315 of May 25, 2016. The Administrative Regulations establish the terms and sequence of administrative procedures (actions) performed by Rospatent, as well as the procedure for interaction between the structural divisions of Rospatent and the officials thereof, between Rospatent and individuals or legal entities, their authorized representatives, other public authorities, institutions and organizations in the process of provision of state services.

From April 29, 2023, the new by-laws were approved by the Order of the Ministry of Economic Development of the Russian Federation No. 107 of February 21, 2023 (by-laws):

- The Rules for preparation, filing and consideration of documents that are the ground for executing legally significant actions for state registration of inventions (hereinafter referred to as the Rules);
- The Requirements to application documents for grant of a patent for invention (hereinafter referred to as the Requirements);
- The composition of information on application for grant of a patent for invention to be published in the Official Bulletin of Rospatent;
- The procedure for conducting information search in relation to the claimed invention when conducting a substantive examination of an application for grant of a patent for invention and submitting a report on it;
- The procedure for publishing a report on information search in relation to the claimed invention;
- The composition of information on grant of a patent for invention to be published in the Official Bulletin of the Rospatent;
- The composition of information specified in a patent for invention;
- Invention patent form.

The Rules updated the 18 formalized templates of applications and requests that may be filed by an applicant at his or her initiative during examination of an application at Rospatent.

The by-laws were supplemented with the provisions updated to take into account changes in the legislation of the Russian Federation and in order to improve the approaches of law enforcement practice to the consideration of applications, as well as to harmonize the Russian regulations with the approaches used in foreign patent systems. In particular, the provisions of the by-laws were changed in terms of:

- the unity of invention requirement (the changes aimed at converging the unity of invention requirement previously applied in the Russian Federation, with the unity of invention requirement established by international agreements which the Russian Federation is a party to);
- assessment of compliance with the requirement of support in the disclosure in the application documents provided for in subparagraphs 1-4 of paragraph 2 of Article 1375 of the Code and submitted on the date of application filing, for a person skilled in the art could implement the invention (changes aimed at improving approaches to conducting such an assessment).

The Rules establish the procedure for involving a Russian scientific or educational organization accredited by Rospatent in conducting a preliminary information search on an application for invention and a preliminary assessment of its patentability, as well as taking into account the results of such work. According to the new Rules, the applicant has the right, on his own initiative, to submit to Rospatent a request to send a copy of the application documents for a patent for invention to a Russian scientific or educational organization accredited by Rospatent.

The list of documents to be attached to the application has been updated. The list of situations when the applicant can make changes to the application documents for an invention has been expanded description, claims, drawing (drawings), other materials, abstract.

The Requirements for application documents are supplemented with the provisions regarding the possibility of submitting a list of nucleotide and/or amino acid sequences in accordance with the WIPO ST.26 standard.

The by-laws approved by the Order of the Ministry of Economic Development of the Russian Federation No. 316 of May 25, 2016, shall be deemed to have lost force.

The Order of the Ministry of Economic Development of the Russian Federation No. 148 of March 15, 2024, introduced amendments to the by-laws and, especially to the above-mentioned Procedures 1 and 2. The amendments set forth approaches to the examination of applications for IT-related inventions and utility models, including specific requirements for the corresponding application documents. Furthermore, the Order of the Ministry of Economic Development of the Russian Federation No. 610 of September 27, 2024, introduced amendments to the by-laws regarding the approaches to the examination of invention applications containing a claim that includes information about the applicability of the invention or method of using the invention for a particular purpose.

The handling of objections to Rospatent decisions taken on the application for invention, to illegitimate actions (inaction) of the officials in connection with the state service provision, is regulated by a separate Federal Law No. 210-FZ “On the organization of state and municipal services provision” of July 27, 2010 (as amended). Rules of filing and processing of the complaints are established by the Resolution of the Government of the Russian Federation No. 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 No. 59-FZ as of May 2,

2006 “On the order of consideration of the requests of the citizens of the Russian Federation” (as amended).

In January 2023, based on the results of a certification audit, Rospatent obtained a certificate of application of the QMS in the Office in accordance with the requirements of the ISO 9001:2015 in the field of international search and international preliminary examination under PCT.

In April 2024, the scope was expanded to the Rospatent’s activities as the PCT Receiving Office and, in December 2024, based on the results of the surveillance audit, the international certification body extended the validity of the ISO 9001:2015 conformity certificate until January 2026. The certificate has been reissued taking into account the activities related to the processing of international applications, conducting international search and international preliminary examination under the international phase of PCT as part of the expanded scope of certification.

In 2023, the work began on the implementation of client-centricity standards in Rospatent in accordance with the In-Office Plan No. 175 of November 28, 2022 approved by the Head of Rospatent as part of the “State for the people” initiative for the social and economic development of the Russian Federation until 2030, being implemented in accordance with the Order of the Government of the Russian Federation No. 2816-r of October 6, 2021.

The requirements of the Standards are developed on the basis of common values and principles approved by the Declaration of client-centricity values. The Declaration proclaims the transition to a client-centric model of public administration and organization of government functions and services, based on ensuring effective and comfortable interaction between people and the state through the analysis of current needs and client experience of a person.

1. LEADERSHIP AND POLICY

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

(a) The quality policy established by top management.

(b) The roles and names of those bodies and individuals responsible for the QMS, as specified by top management.

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

(a) The 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~~2023~~ 2024 ~~(https://rospatent.gov.ru/ru/about/openrospatent/publ-dec-2023~~ https://rospatent.gov.ru/ru/about/openrospatent/publ-dec-2024. The Head of Rospatent is responsible for the development of QMS and the related policy. In 2022, Mr. Yury ZUBOV became the Head of Rospatent.

(b), (c) Supervision of issues related to functioning and improvement of QMS is referred to the competence of Ms. Victoria 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~~ Anton BOBRYSHEV, Acting Director of the Department for the Provision of State Services of Rospatent.

2) Quality Monitoring Center, which includes the following 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;
- Information service and consulting sector;
- 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 QMS;
- 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 analytical processing thereof;
- 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 No. 297 of July 6, 2020, which is updated as the structure of the Center, its tasks, functions, rights, and the procedure for interaction with other divisions of FIPS change. In 2022, the Regulation on the Quality Monitoring Center were supplemented with a provision on recording and analyzing the results of consideration of complaints and other appeals from citizens and legal entities and their statistical processing, taking into account the provisions of the QMS documents, approved by orders of the FIPS Director. The management of the Center is assigned to Ms. Olga ALEKSEEVA, Head of the Center.

3) International Certification Center established in 2020 on the basis of the ISO certification sector. The Center reports directly to the Director of FIPS and is responsible for the following matters:

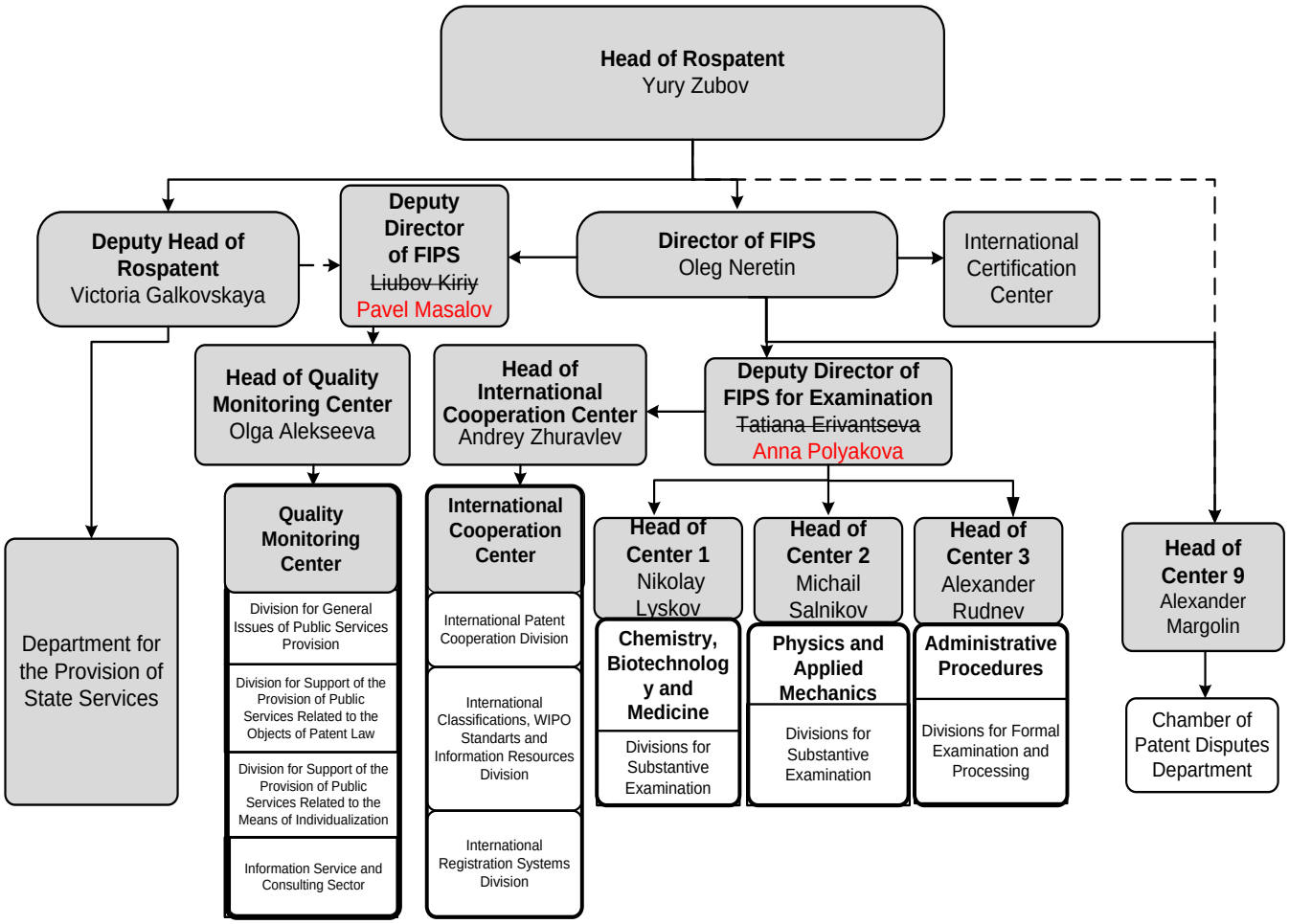
- coordination of work on the development, implementation and improvement of the QMS in FIPS, taking into account the requirements of international standards;
- preparation and conduct of internal audits of the QMS for compliance with the requirements of international standards with the direct participation of the heads of interested structural divisions of FIPS;
- organizing QMS certification audits, including inspection audits, by certification bodies;
- organizing training for FIPS employees in the field of quality management using international standards.

The structure, tasks, functions, rights, interaction with other divisions of FIPS and Rospatent are set forth in the Regulations on the International Certification Center, approved by the Order of the Director of FIPS No. 480 of October 3, 2020 (as amended by the Order of the FIPS Director No. 208 of April 13, 2022).

The management of the International Certification Center is assigned to Ms. Natalya CHIKANOVA, Head of the Center.

4) Center "Chamber of Patent Disputes" department dealing with objections to the decisions taken on the results of examination of applications for inventions. The Center is headed by Mr. Aleksandr MARGOLIN, Interim Head of the Center. The work of the Center is supervised by the Deputy Head of Rospatent Ms. Victoria GALKOVSKAYA and by the FIPS Director.

5) The 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 forms part of the International Cooperation Center established in 2018 and headed by Mr. Andrey ZHURAVLEV.



The Quality Council operates in Rospatent and is chaired by the Head of the IP Office Mr. Yury ZUBOV. Established in 2016, the Quality Council consists of the leading specialists of Rospatent and its subordinate organizations: FIPS (including the specialists of the Department of Legal Representation, who represent the IP Office's interests before the Intellectual Property Court, where Rospatent decisions are contested) and RSAIP. In addition, invited external specialists, in particular patent attorneys, take part in the meetings of the Quality Council.

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 arising in law enforcement practice both at the stage of examination of applications and at the stage of consideration of disputes 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	✓		

Chapter 21 requirement				Extent of compliance		
				full	part	no
		(c)	Communication of quality objectives to the relevant staff at the Authority	✓		
21.09		(a)	Performance of a yearly internal review of the QMS in/to	✓		
		(b)	determine the extent to which the QMS is aligned with Chapter 21	✓		
			determine the extent to which search and examination (S&E) complies with PCT Guidelines	✓		
		(c)	an objective and transparent way	✓		
		(d)	using input incl. information according paragraph 21.29	✓		
		(e)	recording the results	✓		
21.10			Risk and opportunities are addressed that can affect the QMS and the conformity of search and examination	✓		
21.13			Arrangements for establishing risk-based practices to	✓		
	(i)	(a)	understand issues that affect its ability to achieve intended results of the QMS	✓		
		(b)	understand the needs and expectations of interested parties	✓		
	(ii)		identify risks and opportunities related to the performance of the QMS as a basis for planning	✓		
	(iii)		plan and implement actions to address risks and opportunities	✓		
	(iv)		check the effectiveness of the actions taken	✓		
	(v)		continuously update risks and opportunities.	✓		
21.15			Assurance to monitor and adapt to actual workload	✓		
	(i)		Infrastructure in place to ensure that a quantity of staff	✓		
		(a)	sufficient to deal with the inflow of work	✓		
		(b)	which maintains technical qualifications to S&E in all technical fields	✓		
		(c)	which maintains the language facilities to understand languages according to Rule 34	✓		
	(ii)		Infrastructure to provide a quantity of skilled administrative staff	✓		
		(a)	at a level to support the technically qualified staff	✓		
		(b)	for the documentation of records	✓		

Chapter 21 requirement				Extent of compliance		
				full	part	no
	(iii)		Ensuring appropriate equipment to carry out S&E	✓		
	(iv)		Ensuring documentation according to Rule 34	✓		
	(v)	(a)	Instructions to help staff understand and act according to the quality criteria and standards	✓		
		(b)	Instructions to follow work procedures accurately and they are kept up-to-date.	✓		
	(vi)	(a)	Training and development program to ensure and maintain necessary skills in search and examination	✓		
		(b)	Training and development program to ensure awareness of staff to comply with the quality criteria and standards.	✓		
	(vii)	(a)	System in place for monitoring resources required to deal with demand	✓		
		(b)	System in place for monitoring resources required to comply with the quality standards in S&E	✓		
21.16	(i)		Control mechanisms to ensure timely issue of S&E reports	✓		
	(ii)		Control mechanisms regarding fluctuations in demand and backlog	✓		
21.17	(i)		Internal quality assurance system for self-assessment	✓		
		(a)	for compliance with S&E Guidelines	✓		
		(b)	for channeling feedback to staff	✓		
	(ii)		System for measurement of data and reporting for continuous improvement	✓		
	(iii)		System for verifying the effectiveness of actions taken to correct deficient S&E work, eliminate the causes and prevent issues from recurring	✓		
21.19		(a)	Contact person helping identify best practice between Authorities	✓		
		(b)	Contact person fostering continual improvement	✓		
		(c)	Contact person providing for effective communication with other Authorities for feedback and evaluation	✓		
21.20	(i)	(a)	Appropriate system for handling complaints	✓		
		(b)	Appropriate system for taking preventive/corrective actions	✓		
		(c)	Appropriate system for offering feedback to users	✓		

Chapter 21 requirement				Extent of compliance		
				full	part	no
	(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	✓		
21.23		(a)	Material making up the reference of quality procedures and processes for staff and management has been prepared and distributed	✓		
		(b)	Media available to support the reference material	✓		
		(c)	Document control measures are taken	✓		
21.24			Items which should be documented in the reference of quality procedures and processes	✓		
	(i)		Quality policy of the Authority and commitment to QMS	✓		
	(ii)		Scope of QMS	✓		
	(iii)		Organizational structure and responsibilities	✓		
	(iv)		Documented processes carried out in the Authority	✓		
	(v)		Resources available to carry out processes and implementing the procedures	✓		
	(vi)		Description of the interaction between the processes and the procedures of the QMS.	✓		
21.25	(i)		Records of which documents are kept and where they are kept	✓		
	(ii)		Records of results of management review	✓		
	(iii)		Records about training, skills and experience of staff	✓		
	(iv)		Records of evidence of conformity of processes, resulting products and services in terms of quality standards	✓		
	(v)		Records of results of reviews of requirements relating to products	✓		
	(vi)		Records of the S&E process carried out on each application	✓		

Chapter 21 requirement				Extent of compliance		
				full	part	no
	(vii)		Records of data allowing individual work to be tracked	✓		
	(viii)		Records of QMS audits	✓		
	(ix)		Records on actions taken re. non-conforming products	✓		
	(x)		Records on actions taken re. corrective actions	✓		
	(xi)		Records on actions taken re. preventive actions	✓		
	(xii)		Records referring to search process documentation	✓		
21.26	(i)		Recording of the databases consulted during search	✓		
	(ii)		Recording of keywords, combination of words and truncations during search	✓		
	(iii)		Recording of the languages used during search	✓		
	(iv)		Recording of classes and combinations thereof consulted during search	✓		
	(v)		Recording of a listing of all search statements used in databases consulted		✓	
	(vi)		Records about other information relevant to the search	✓		
	(vii)		Records about limitation of search and its justification	✓		
	(viii)		Records about lack of clarity of the claims	✓		
	(ix)		Records about lack of unity	✓		
21.27			Report on its own internal review processes	✓		
21.28-21.30			Additional information on further inputs to its internal reviews		✓	
21.31			Initial report called for by paragraph 21.31	✓		

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

(a) the effectiveness of the QMS; and

(b) that the process of continual improvement progresses.

(a), (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 2020, the International Certification Centre became responsible for coordination of the QMS development, implementation and improvement, taking into account requirements of the international standards.

In 2021, Rospatent started its work on certification of international search and international preliminary examination processes under the PCT in accordance with the requirements of ISO 9001-2015 (see Clause 21.10).

In January 2023, based on the results of a certification audit, Rospatent obtained a certificate of application of QMS in accordance with the requirements of ISO 9001:2015 international standard in the field of international search and international preliminary examination within the framework of the PCT.

The Order of the FIPS Director No. 197 of April 16, 2024, expended the scope of the QMS to incorporate activities related to the implementation of the Rospatent's functions as the PCT Receiving Office.

In October 2024, the certification body conducted the second surveillance expanding audit of the PCT QMS for compliance with the ISO 9001:2015 standard requirements. Based on the results, the auditor prepared a report containing conclusions regarding the possibility of extending the certificate of compliance validity period and expanding the scope of certification. In December 2024, based on the results of the surveillance audit, the international certification body extended the validity of the ISO 9001:2015 conformity certificate until January 2026.

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.

The information on results of inspections of examination quality, new procedures, other information concerning the activity of Rospatent and FIPS is forwarded 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 by the relevant staff at the respective Authority.

(a) Administrative operational inspections are carried out on the instructions of the Head of Rospatent. Planned inspections of the completeness and quality of the provision of public services are carried out in accordance with the provisions of the Administrative Regulations. Inspections are carried out by the Department for the Provision of Public Services of Rospatent and the Quality Monitoring Center of FIPS, International Patent Cooperation Division, and heads of examination departments.

Based on the results of the inspections, reporting documents are submitted 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 forwarded 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 9, namely:

to determine the extent to which the QMS is based on Chapter 21 (cf. paragraphs 21.27, 21.29(i));

to determine the extent to which Search and Examination work complies with PCT Guidelines (cf. paragraphs 21.27, 21.29(i));

(c) in an objective and transparent way (cf. paragraph 21.27);

(d) using input including information according to paragraphs 21.29 (ii)-(vi);

(e) recording the results (cf. paragraph 21.30).

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.

Based on the results of the inspection, a report is prepared. Proposals for improving the QMS are recorded and analyzed.

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 leadership encourages the practice of ensuring that risks and opportunities that may affect its QMS and compliance are taken into account. In 2021, the Office started its work on certification of international search and international preliminary examination processes under PCT in accordance with the requirements of ISO 9001:2015. The following documents were approved in this regard:

- Policy in the field of quality (Order of the FIPS Director No. 184 of May 5, 2021);
- Quality Guidelines for International Search and International Preliminary Examination Processes under the Patent Cooperation Treaty (Order of the FIPS Director No. 501 of November 26, 2021);
- Procedure for internal audit in relation to the processes of international search and international preliminary examination under PCT (Order of the FIPS Director No. 501 of November 26, 2021);
- Procedure for QMS Analysis by FIPS leadership in relation to the processes of international search and international preliminary examination under PCT (Order of the FIPS Director No. 501 of November 26, 2021);
- Objectives in the field of quality in the area of activity of the Center for International Cooperation (Order of the FIPS Director 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 PCT were carried out.

Based on the results of internal audits carried out in 2021, an Action Plan has been approved to eliminate the identified comments and improve the QMS (Order of the FIPS Director No. 28 of January 24, 2022).

The forms of QMS documents and reports have been approved in respect of the workflow on the processes of international search and international preliminary examination under the Patent Cooperation Treaty (Order of the FIPS Director No. 18/23 of March 25, 2022).

Amendments have been made to the following current QMS documents (Order of the FIPS Director No. 177 of March 30, 2022):

- Quality Guidelines as applied to the International Search and International Preliminary Examination under PCT;
- Internal Audit procedure as applied to the processes of International Search and International Preliminary Examination under the Patent Cooperation Treaty;
- Procedure for QMS Analysis by FIPS leadership as applied to the processes of International Search and International Preliminary Examination under the Patent Cooperation Treaty.

Quality Goals for 2022 in respect of the PCT QMS and the Plan for their achievement (Order of the FIPS Director No. 171 of March 28, 2022) have been approved.

In November 2022, a certification audit was carried out by a third party, according to the results of which the QMS as applied to the processes of international search and international preliminary examination under the PCT was recognized as complying with the requirements of ISO 9001:2015 international standard.

In January 2023, based on the results of consideration by the international certification body of the certification audit report, a certificate of compliance of the PCT QMS with the requirements of ISO 9001:2015 international standard No. 20100223015602 of January 20, 2023, was received, valid until January 19, 2026. The certification was carried out in accordance with auditing and certification procedures; in this regard, the QMS is subject to regular surveillance audits by the international certification body.

The quality goals for 2023 in the field of the PCT QMS and the Plan for their achievement were approved (Order of the Director of FIPS No. 227 of May 24, 2023).

In October 2023, in order to assess the effectiveness of the QMS, internal audits of the main and supporting processes of the international search and international preliminary examination within the framework of the Patent Cooperation Treaty were carried out (Order of the Director of FIPS No. 381 of September 5, 2023).

In November 2023, the certification body conducted the first surveillance audit of the PCT QMS for compliance with the requirements of ISO 9001:2015 standard, in the result of which a positive decision was made to extend the validity of the certificate of compliance No. 20100223015602 of January 20, 2023. The surveillance audit report is registered in the information database of the certification body.

In 2024, Rospatent decided to extend the QMS scope to include its work as a PCT Receiving Office (Order of the Director of FIPS No. 197 of April 16, 2024). The forms of the QMS documents

and reports related to examination of international applications, conducting international search and international preliminary examination under PCT in international phase were improved and adopted (Order of the Director of FIPS No. 29/23 of April 19, 2024).

The 2024 Quality goals related to the PCT QMS and the Plan for their achievement were also approved (Order of the FIPS Director No. 225 of May 2, 2024).

In September 2024, the Order of the FIPS Director No. 365 of August 20, 2024, established the PCT QMS Internal Audit Program to assess implementation of the Plan for Achievement of the FIPS Quality Goals and the assessment of the FIPS QMS compliance with internal regulatory documentation and the requirements of the ISO 9001:2015 standard.

Based on the results of the internal audit, amendments were made to the PCT QMS Manual regarding activities of the Receiving Office (Order of the Director of FIPS No. 492 of November 7, 2024). In October 2024, the certification body conducted the second surveillance expanding audit of the PCT QMS to verify compliance with the iso 9001:2015 standard requirements. Based on the results the international certification body extended the validity of the ISO 9001:2015 conformity certificate until January 2026.

2. RISK-BASED PRACTICES

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

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

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

21.13 Arrangements for establishing risk-based practices

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

(i) (a) understand issues that affect its ability to achieve intended results of the QMS, and

(b) understand the needs and expectations of interested parties;

(ii) identify risks and opportunities related to the performance of the QMS as a basis for planning;

(iii) plan and implement actions to address risks and opportunities;

(iv) check the effectiveness of the actions taken; and

(v) continuously update risks and opportunities.

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

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

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

- registering complaints of the applicants, in particular, concerning the quality of provided State service — granting of a patent for an invention including the completeness and quality of searches and the examination of applications for inventions;
- carrying out routine quality control of the searches and documents sent to the applicant, routine and random checks, in particular, of completeness and quality of the State service related to the issuance of a patent for an invention;
- 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 the sufficient number 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 ~~2023~~ 2024, the following measures were taken with regard to staff:

- in order to increase labor efficiency, about 30% of FIPS employees perform work duties remotely;
- 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;
- FIPS internship program continues to be implemented, which is designed to attract new specialists to perform patent examination;
- in order to enhance staff skills, FIPS keeps on sending the employees for training to RSAIP to obtain education in the field of intellectual property; moreover, the staff members are regularly participating in WIPO training activities. In addition, FIPS launched a Master's program and is training employees in the area of "Innovation".
- the Siberian Center of FIPS ~~increased the number of examiner staff; there are 75~~ counts 74 specialists in total ~~working there~~, ~~60~~ 59 of them are examiners (the Trademark Applications Examination Department has ~~41~~ 43 examiners, the Utility Models Department has ~~19~~ 16 examiners).
- the Volga FIPS Center ~~was created~~ increased the number of examiner staff, ~~which~~ and employs a total of ~~19~~ 26 persons, of which ~~11~~ 15 are examiners of the (Department for trademark application examination ~~of the Volga FIPS Center~~);
- ~~a~~the Department of higher education increased the number of the ~~consisting of 6 person~~ teaching staff up to 11 persons ~~was created.~~;
- the Ural Center of FIPS has been established, which includes a department for processing and storing retrospective application materials, and functionality for processing and accounting of state duties has been added. Personnel recruitment is currently in progress;
- the Center for Commercialization Support has been established, the main tasks of which are to support the commercialization of technical and technological solutions under legal protection, comprehensive assistance in creating innovative products based on intellectual property.

Concerning staffing levels, it should be noted that in ~~2023~~ 2024 the total number of examiners constituted ~~911~~ 924, of whom ~~447~~ 444 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 ~~26~~ 25, 10 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:

- the Center 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 Center 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 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, pharmaceutics, 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 ~~2023~~ 2024, the examiners had access to a commercial database: STN International.

In ~~2023~~ 2024, within the scope of the “National Subscription” Project, FIPS got free access to the following resources: a commercial database QUESTEL – ORBIT, ~~SPRINGER NATURE's electronic resources, John Wiley & Sons Inc., the resources of EBSCO Information Services GmbH., electronic versions of the journals “Advances in Physical Sciences”, “Quantum Electronics”, as well as electronic resources of the V. Steklov Mathematical Institute of~~ RAS “Springer Nature Protocols and Methods” database, “Springer Materials” database, Nature magazine electronic resources, as well as electronic versions of the journals of FBGU “Russian Academy of Sciences”.

In ~~2023~~ 2024, the examiners have access from their workstations to 19 periodicals of scientific, technical topics, and ~~5~~ 7 periodicals of patent-related legal topics subscribed in electronic form.

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 intra-office 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 are carried out under the PCT International Search and Preliminary Examination Guidelines.

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 in respect of information search, 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 of the 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 International Patent Classification (IPC) and Cooperative Patent Classification (CPC) training is also conducted.

3.4 Internal training plans are quarterly summarized by the Scientific and Educational Center (SEC FIPS) and approved by the Director of FIPS. Control over the implementation of the approved plan also falls under the responsibility of SEC FIPS. More than 250 training events are held annually in structural divisions as part of internal training (cl. 3.1, 3.2, 3.3.).

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 RSAIP 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 RSAIP.
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 2021,~~ As part of the measures to develop and introduce QMS 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.

From 2020 to 2024, more than 70 FIPS employees have undergone training in QMS programs.

7. Since 2020, FIPS Scientific and Educational Center has been regularly training FIPS expert staff to improve their English proficiency. Training is conducted differentially at 5 levels by a full-time teacher of SEC FIPS. More than 100 specialists have been trained, and the project is still ongoing.

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 of International Classifications and Information Support of Search in the Field of Patent Law Objects jointly with 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.

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 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) As a result of the annual analysis of distribution throughout various fields of science and technology (IPC headings) of applications received by FIPS, if a significant disbalance in the workload of examiners from various departments is revealed, a more even distribution between the departments of the IPC headings assigned to them is administratively made.

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 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 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.

The IPCD keeps records of data using approved forms of QMS documents and reports as applied to the workflow on the processes of international search and international preliminary examination under the Patent Cooperation Treaty (see cl. 21.10), analyzes the data obtained to assess the achievement of established QMS performance indicators and to assess the degree of achievement of goals in the field of QMS quality, as well as analyzes compliance with the terms for submission of reporting documents by examiners.

According to the 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, FIPS Deputy Director, who supervises 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 Chief, International Patent Cooperation Division, e-mail: amv20otd@rupto.ru

Ms. Elena SOROKINA, Deputy Chief, 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" No. 59-FZ as of May 2, 2006 (as amended);
- Federal law "On organization of state and municipal service provision" No. 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 No. 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 Rospatent No. 163 as of December 11, 2020, registered with the Ministry of Justice of the Russian Federation 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 (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 No. 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:

- satisfiers 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;

- 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 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 situation 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 applicant/patent holder 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 applicants/patent holders, 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 interested persons 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.

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 comments from interested persons on the projects of regulatory documents, available on the Federal Portal of Draft Regulatory Legal Acts http://regulation.gov.ru and 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 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);
- Methodological materials and recommendations developed by FIPS to help Russian applicants;
- 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.

The Public declaration of tasks and objectives Rospatent for the year of ~~2023~~ 2024 is represented on the official website (~~https://rospatent.gov.ru/ru/about/openrospatent/publ-dec-2023~~ https://rospatent.gov.ru/ru/about/openrospatent/publ-dec-2024).

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 e-mail and PCT-EDI and ePCT systems.

Rospatent does not practically contact with designated and selected Offices via mail, fax and e-mail 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 2022 application copies in electronic form filed to twelve 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 by documenting the procedures and processes affecting the quality of work as a reference for staff and management at the Authority (see paragraph 21.23).

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

21.23 The material that makes up the reference for staff and management at the Authority serves to document the procedures and processes affecting the quality of work, such as classification, search, examination and related administrative work. In particular, the reference indicates where to find instructions on the procedures to be followed.

For the purposes of this report indicate:

(a) the documents making up the reference that have been prepared and distributed;

(b) the media on which they are supported (e.g. Internal Publication, Internet, Intranet); and

(c) document control measures taken e.g. version numbering, access to latest version.

The 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. 107 of February 21, 2023, 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 adopted by the order of Rospatent No. 236 of December 27, 2018.

The issues of classification of applications according to IPC and CPC are considered in the Guidelines ~~for~~ to 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 (Order of Rospatent No. 146 of December 20, 2002);
- 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 PCT (Order of the Director of FIPS No. 135 of April 8, 2021);

- Procedure for the cooperation of FIPS divisions during the performance of work related to different types of search and examination in accordance with international agreements (Order of the Director of FIPS No. 536 of December 7, 2021);

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

- Quality Guidelines for International Search and International Preliminary Examination processes under PCT (Order of the Director of FIPS No. 177 of March 30, 2022 as amended by Order of the Director of FIPS No. 492 of November 7, 2024);
- Internal Audit Procedure for International Search and International Preliminary Examination processes under PCT (Order of the Director of FIPS No. 177 as of March 30, 2022);
- Procedure for QMS analysis by FIPS management in relation to the processes of International Search and International Preliminary Examination under PCT (Order of the Director of FIPS No. 177 of March 30, 2022).

21.24 Indicate whether the material making up the reference of quality procedures and processes include the following:

(i) the quality policy of the Authority including a clear statement of commitment to the QMS from top management;

(ii) the scope of the QMS, including details of and justification for any exclusions;

(iii) the organizational structure of the Authority and the responsibilities of each of its departments;

(iv) the documented processes carried out in the Authority such as receipt of incoming applications, classification, distribution, search, examination, publication and support processes, and procedures established for the QMS, or references to them;

(v) the resources available for carrying out the processes and implementing the procedures; and

(vi) a description of the interaction between the processes and the procedures of the QMS.

(i) The Office policy in the field of quality is reflected in the Public Statement of goals and objectives of Rospatent for ~~2023~~ 2024 ~~https://rospatent.gov.ru/ru/about/openrospatent/publ-dec-2023~~ https://rospatent.gov.ru/ru/about/openrospatent/publ-dec-2024).

(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 8.

(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 and the 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.

In accordance with amendments made to a number of by-laws that came into force on April 29, 2023 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 (similar Rules have been released for utility models);
- The order of information search in respect of the claimed invention in the course of substantive examination of application for grant of a patent for invention and providing a report thereon;
- The procedure for publishing information search report in respect to the claimed invention;
- 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.

In 2024, these documents were amended by Order of the Ministry of Economic Development of the Russian Federation No. 148 of March 15, 2024 regarding the approaches to assessing the patentability of claimed invention and utility model, as well as concerning features and objects that are excluded from the search.

The Rules for drafting, filing and reviewing documents that serve as the basis for legally significant actions for state registration of inventions and the Requirements for application documents for a patent for invention were also amended by Order of the Ministry of Economic Development of the Russian Federation No. 610 of September 27, 2024 regarding the verification of the inventive step for claimed objects related to the use of a product or method for a specific purpose.

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 explanations regarding the issues of determining the subject of search, the field and scope of search when 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.

Since 2011 the examiners have been required to document the search process, in accordance with the Instructions for preparing the search history and the resulting document set (Internal Orders No. 159/16 of June 1, 2011, and No. 195/16 of 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 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 annual reports in accordance with paragraph 21.31(b). Authorities should submit each report in the form of a full report, making the differences from the previous year's report clear, for example using "track changes" or other form of highlighting.

[End of document]