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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.

Abbreviations

- Rospatent – Federal Service for Intellectual Property
- FIPS – Federal State Budgetary Institution “Federal Institute of Industrial Property”, a subordinate body of Rospatent
- RSAIP – Federal State Budgetary Institution for Higher Education “Russian State Academy of Intellectual Property”, a subordinate body of Rospatent

Normative Reference for QMS besides Chapter 21 of the Guidelines

The grant of legal protection to intellectual property (IP), in particular to inventions, is governed by Part IV of the Civil Code of the Russian Federation (the Code). Part IV was enacted by Federal Law No. 230-FZ "On the Enactment of Part Four of the Civil Code of the Russian Federation" of December 18, 2006, and came into force on January 1, 2008 (as amended). Since October 1, 2014, amendments to Part IV of the Code have been in effect. These amendments are aimed at improving patent quality and the reliability of legal protection, as well as at harmonizing substantive and procedural rules for the protection of inventions with international standards.

The functions of the federal executive body for IP in the Russian Federation are vested in Rospatent. Its authority to receive and register invention applications, conduct examinations, and grant patents (within the framework of public service provision) is established by Resolution of the Government of the Russian Federation No. 218 of March 21, 2012 (as amended).

Rospatent operates under the jurisdiction of the Ministry of Economic Development of the Russian Federation, which is the federal executive body responsible for IP-related legal regulation. In particular, the Ministry approves regulations that set out Requirements for Patent Application Documents for Inventions and Utility Models, as well as the Rules for Their Preparation, Filing, and Consideration.

In 2020, Part IV of the Civil Code was amended by Federal Law No. 217-FZ "On Amending Part Four of the Civil Code of the Russian Federation" of July 20, 2020, which introduced a new element to the application – a three-dimensional (3D) representation of an invention or utility model in electronic form. Applicants may use this electronic format to describe the claimed invention or utility model. Furthermore, Federal Law No. 217-FZ provides for the grant of a patent for an invention or utility model in the form of an electronic document. A traditional paper patent may also be issued at the applicant's request. These changes are designed to expand the list of application materials, allowing for a more exhaustive disclosure of the invention and automating the information search process, thereby improving the patent issuance procedure through the use of modern technologies. Federal Law No. 217-FZ entered into force on January 17, 2021.

Federal Law No. 262-FZ "On Amending Part Four of the Civil Code of the Russian Federation" of July 31, 2020, introduced a new optional procedure for the registration of inventions and utility models and the grant of patents. This procedure involves a preliminary information search and a preliminary patentability assessment of the claimed invention or utility model, conducted by Russian scientific and educational organizations accredited by Rospatent. This new procedure is optional and is carried out at the applicant's initiative. The Code stipulates that the results of the preliminary information search and patentability assessment must be taken into account during

the examination of the application by Rospatent. The use of findings from specialists engaged in scientific activities during the examination is expected to improve the quality of granted patents.

In addition, Federal Law No. 262-FZ introduced other amendments, particularly regarding the possibility of amending the documents of an application for an invention or utility model after receiving a preliminary information search report when submitting a request for substantive examination of an invention application. The Law also clarified the start date for the time limit for filing a request for substantive examination of an invention application for international applications that have entered the national phase with Rospatent. These procedural changes came into force 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 part of the implementation of the procedures provided for by Federal Law No. 262-FZ, as of ~~December 2024~~ August 2025, Rospatent had accredited a total of ~~8~~9 educational institutions of higher education and scientific organizations to conduct preliminary information searches for claimed inventions or utility models and preliminary assessments of patentability. Representatives of these organizations passed the relevant examinations at FIPS. Of the 9 accredited organizations, one has since terminated its activities.

- Due to the ongoing administrative reform in the Russian Federation, Rospatent Order No. 163 of December 11, 2020, approved new Administrative Regulations, which took effect on June 19, 2021. These Regulations incorporate the amendments introduced to the Code by Federal Law No. 217-FZ and Federal Law No. 262-FZ, and replaced the previous Administrative Regulations approved by 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 its structural divisions and officials, and between the IP Office and applicants, their representatives, other public authorities, institutions, and organizations in the process of providing the state service for the state registration of inventions and the issuance of patents.

On April 29, 2023, new Regulations approved by Order of the Ministry of Economic Development of the Russian Federation No. 107 of February 21, 2023, came into effect. These Regulations comprise:

- Rules for the Preparation, Filing, and Consideration of Documents Forming the Basis for Legally Significant Actions for the State Registration of Inventions (Rules);
- Requirements for Application Documents for the Grant of a Patent for an Invention (Requirements);
- Composition of Information on an Application for the Grant of a Patent for an Invention to Be Published in the Official Bulletin of Rospatent;
- Procedure for Conducting an Information Search in Relation to a Claimed Invention During the Substantive Examination of a Patent Application and for Submitting a Report Thereon;
- Procedure for Publishing an Information Search Report for a Claimed Invention;
- Composition of Information on the Grant of a Patent for an Invention to Be Published in the Official Bulletin of Rospatent;
- Composition of Information Specified in a Patent for an Invention;
- Form of the Invention Patent.

Approved as annexes to the Rules are 18 updated formalized templates of applications and requests, available for applicants to file at their discretion during the examination process at Rospatent.

These Regulations have been updated to incorporate changes in the legislation of the Russian Federation, to improve enforcement practices in the consideration of applications, and to harmonize Russian regulations with cutting-edge global practices and approaches. Key amendments include provisions concerning:

- The unity of invention requirement – the changes are aimed at aligning the Russian practice with the unity of invention requirement established by international agreements to which the Russian Federation is a party.

- The assessment of sufficient disclosure – the amendments refine the approaches to assessing whether the disclosure in the application documents, as filed, supports the invention to the extent that a person skilled in the art can carry it out, in accordance with subparagraphs 1-4 of paragraph 2 of Article 1375 of the Code.

The Rules establish procedures not only for drafting, filing, and examining invention applications, but also for engaging a Rospatent-accredited Russian scientific or educational organization to conduct a preliminary information search and patentability assessment. Furthermore, they outline how the results of this work are to be taken into account. Under the new Rules, an applicant has the right to independently submit a request to Rospatent, asking that a copy of the invention patent application documents be sent to an accredited organization.

The list of documents required to be submitted with an application has been updated. Furthermore, the range of scenarios in which an applicant is permitted to amend application documents – such as the description, claims, drawings, other materials, and the abstract – has been expanded.

The requirements for application documents have been supplemented with provisions allowing for the submission of nucleotide and/or amino acid sequence listings in accordance with WIPO Standard ST.26.

The Regulations previously approved by Order of the Ministry of Economic Development of the Russian Federation No. 316 of May 25, 2016, has ceased to be effective.

In 2024, amendments were introduced to the current Regulations, including the relevant updates to the above-mentioned Procedures 1 and 2, via Order of the Ministry of Economic Development of the Russian Federation No. 148 of March 15, 2024. These amendments established specific approaches for examining patent applications for inventions and utility models related to information technology, as well as the corresponding requirements for their application documents. Subsequently, further amendments were made by Order of the Ministry of Economic Development of the Russian Federation No. 610 of September 27, 2024, concerning the examination of inventions characterized in the claims as the use of a product or method for a specific purpose (purposive use), and the requirements for drafting claims for such inventions.

The procedure for considering objections against Rospatent's decisions on invention applications and against unlawful actions or failures to act by its officials in the provision of the state service, is governed by a separate Federal Law No. 210-FZ of July 27, 2010, "On the Organization of the Delivery of State and Municipal Services" (as amended). The specific rules for filing and processing such complaints are established by Resolution of the Government of the Russian Federation No. 840 of August 16, 2012 (as amended).

Requests from applicants, right holders, and other parties concerning other matters related to Rospatent's activities are processed in accordance with Federal Law No. 59-FZ of May 2, 2006, "On the Procedure for Considering Appeals from Citizens of the Russian Federation" (as amended).

In January 2023, following a successful certification audit, Rospatent obtained a certificate confirming the application of the Quality Management System (QMS) in accordance with the

requirements of the international standard ISO 9001:2015 for activities related to international search and international preliminary examination under the Patent Cooperation Treaty (PCT).

In October 2024, the certification body conducted the second supervisory expanding audit of the PCT QMS for compliance with the requirements of the ISO 9001:2015 standard. Based on the results, the auditor prepared a report with conclusions on the possibility of extending the validity period of the certificate of compliance and expanding the scope of certification. ~~The decision of the certification body to reissue the certificate, taking into account the expansion of the scope, is expected within the scheduled time frame.~~ In accordance with the decision of the international certification body, the certificate was reissued taking into account the expansion of the certification scope.

In 2023, Rospatent started the implementation of Customer-Focused Standards in accordance with the In-Office Action 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 Customer-Focused Values that 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 customer 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 Rospatent for ~~2024~~ 2025 (available at ~~https://rospatent.gov.ru/ru/about/openrospatent/publ-dec-2024~~ https://Rospatent.gov.ru/content/uploadfiles/1/public-dekl-2025.pdf). The Head of Rospatent is responsible for the development of QMS and the related policies. Mr. Yury ZUBOV was appointed Head of the IP Office in 2022.

(b), (c) Supervision of matters related to the functioning and improvement of the QMS falls within the competence of Ms. Victoria GALKOVSKAYA, Deputy Head of Rospatent.

The organizational structure of the QMS includes the following ~~divisions~~ units:

1. **Department for the Provision of State Services of Rospatent**, headed by Mr. Anton BOBRYSHEV, its ~~Acting~~ Director.

2. **Quality Monitoring Center of FIPS**, which comprises the following divisions:
    - Division for General Matters of Public Services Provision;
    - Division for Support of Public Services Related to Objects of Patent Law;
    - Division for Support of Public Services Related to Means of Individualization;
    - Information Service and Consulting Sector.

The Center is responsible for general quality control matters, including:

- Providing systematic (including operational) and methodological support to examination divisions;
- Monitoring the quality of public services, specifically the functioning of the QMS, actions and documents prepared by examiners and other FIPS employees during administrative procedures and complaint investigations, and the timeliness of administrative actions;
- Developing proposals for organizational, methodological, technological, informational, and educational measures aimed at eliminating violations identified during monitoring and their root causes;
- Processing and analytically reviewing complaints related to the provision of public services;
- Analyzing FIPS activity quality indicators.

The structure, tasks, functions, authority, and cooperation procedures with other divisions of FIPS and Rospatent are defined by the Regulation on the Quality Monitoring Center, approved by Order No. 297 of the Director of FIPS dated July 6, 2020. The Regulation is updated as changes occur in the Center's structure, tasks, functions, authority, and interaction procedures with other FIPS divisions. In 2022, the Regulation was supplemented with provisions on recording and analyzing the results of complaints and other appeals from individuals and legal entities, including their statistical processing, in accordance with QMS documentation requirements approved by orders of the Director of FIPS (Order No. 129 of the Director of FIPS dated March 18, 2022).

Management of the Center is entrusted to Ms. Olga ALEKSEEVA, its Director.

3. **International Certification Center of FIPS**, established in 2020 on the basis of the ISO Certification Sector, which reports directly to the Director of FIPS.

The Center is responsible for the following areas:

- coordinating the development, implementation, and improvement of the QMS at FIPS in accordance with international standards;
- preparing and conducting internal QMS audits to verify compliance with international standards, with the direct participation of heads of relevant FIPS structural divisions;
- organizing QMS certification audits, including surveillance audits, by certification bodies;
- organizing training for FIPS employees in quality management based on international standards.

The structure, tasks, functions, authority, and procedures for interaction with other divisions of FIPS and Rospatent are established by the internal Regulation on the International Certification Center, approved by Order No. 480 of the Director of FIPS dated November 3, 2020 (as amended by Order No. 208 of the Director of FIPS dated April 13, 2022).

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

The structure, tasks, functions, rights, interaction with other divisions of FIPS and Rospatent are established by an in-Office document - the Regulations on the International Certification Center, approved by the Order of the Director of FIPS No. 480 of 03.11.2020 (as amended by the Order of the Director of FIPS No. 208 of April 13, 2022).

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

4. **Chamber of Patent Disputes** is dealing with objections to the decisions taken on the results of examination of applications for inventions. The Chamber is headed by Mr. Aleksandr MARGOLIN, its Acting Head. The Chamber's activities are supervised by Viktoria GALKOVSKAYA, Deputy Head of Rospatent, and by Mr. Oleg NERETIN, Director of FIPS.

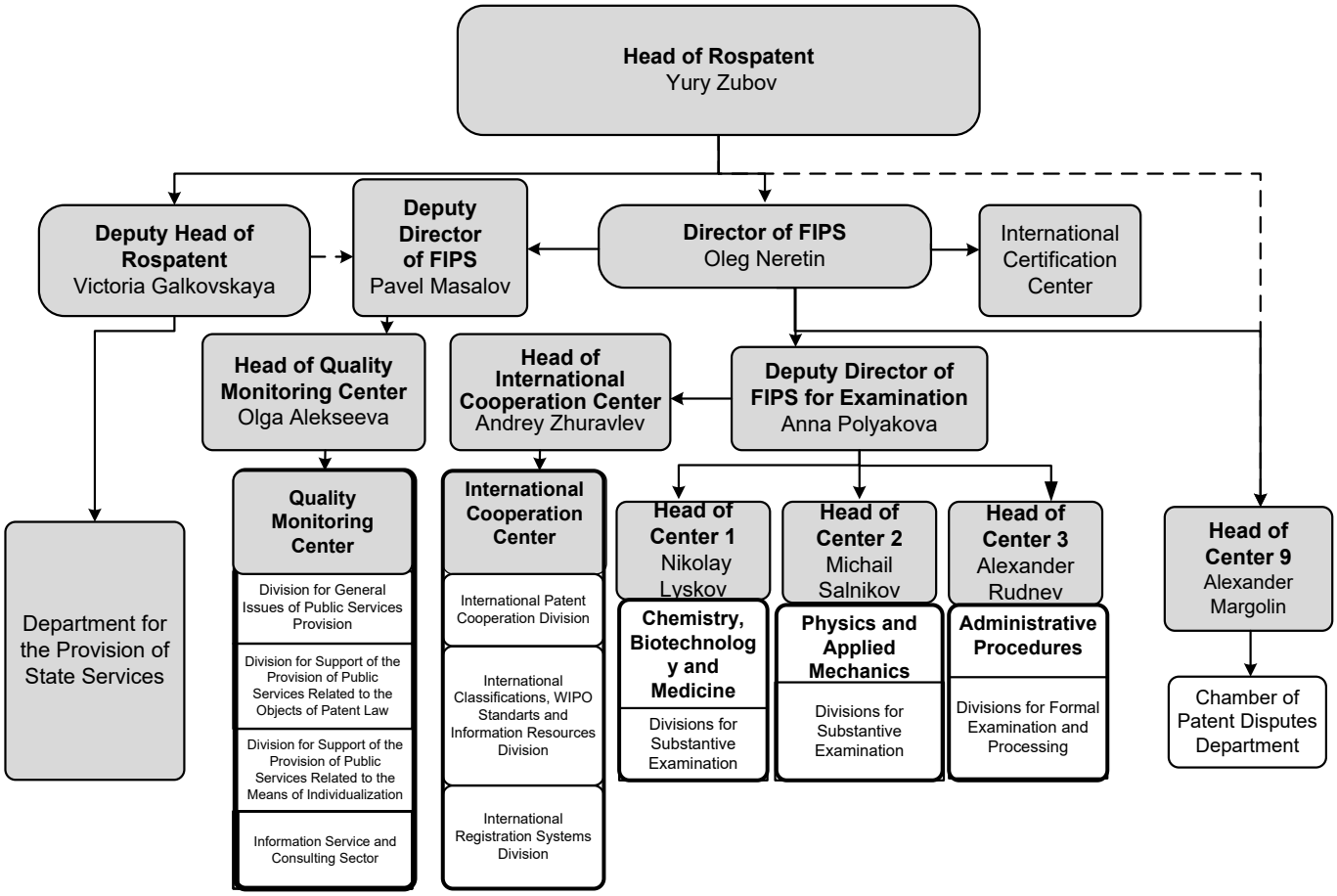
5. **International Patent Cooperation Division of FIPS** is dealing with quality check of the international search reports, written opinions and international preliminary examination reports. The Division is headed by Ms. Liubov SENCHIKHINA. The Division forms part of the International Cooperation Center, established in 2018 and headed by Mr. Andrey ZHURAVLEV.

The Rospatent Quality Council was established in 2016 and comprises leading specialists from the IP Office and its subordinate organizations – RSAIP and FIPS (including specialists from the Legal Representation Department who participate in the proceedings before the IP Court where Rospatent decisions are challenged). Additionally, invited external specialists, particularly patent attorneys, participate in the Council's meetings.

The main tasks of the Rospatent Quality Council are:

- ensuring uniformity in the practical application of the Civil Code and regulations, particularly during the examination of invention applications; and
- setting objectives for monitoring the completeness and quality of state services, analyzing monitoring results, and coordinating actions aimed at quality improvement.

During its meetings, the Quality Council discusses current outstanding issues arising in law enforcement practice at both the application examination and dispute resolution stages, making high-level decisions that must be followed by all subdivisions. The minutes of the Quality Council meetings are published on the official Rospatent website (available at: https://rospatent.gov.ru/ru/about/consult/sovet_po_kachestvu) and are openly accessible. The Council decisions are mandatory for all FIPS divisions. The Quality Council is chaired by the Head of Rospatent.



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	✓		

Chapter 21 requirement				Extent of compliance		
				full	part	no
		(b)	Quality objectives are reviewed	✓		
		(c)	Communication of quality objectives to the relevant staff at the Authority	✓		
21.09		(a)	Performance of a yearly internal review of the QMS in/to	✓		
		(b)	determine the extent to which the QMS is aligned with Chapter 21	✓		
			determine the extent to which search and examination (S&E) complies with PCT Guidelines	✓		
		(c)	an objective and transparent way	✓		
		(d)	using input incl. information according to 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 search and examine in all technical fields	✓		
	(ii)		Infrastructure to provide a quantity of skilled administrative staff	✓		
		(a)	at a level to support the technically qualified staff	✓		
		(b)	for the documentation of records	✓		
	(iii)		Ensuring appropriate equipment to carry out S&E	✓		
	(iv)		Ensuring documentation according to Rule 34	✓		
	(v)	(a)	Instructions to help staff understand and act according to the quality criteria and standards	✓		

Chapter 21 requirement				Extent of compliance		
				full	part	no
		(b)	Instructions to follow work procedures accurately and they are kept up-to-date.	✓		
	(vi)	(a)	Training and development program to ensure and maintain necessary skills in search and examination	✓		
		(b)	Training and development program to ensure awareness of staff to comply with the quality criteria and standards.	✓		
	(vii)	(a)	System in place for monitoring resources required to deal with demand	✓		
		(b)	System in place for monitoring resources required to comply with the quality standards in S&E	✓		
21.16	(i)		Control mechanisms to ensure timely issue of S&E reports	✓		
	(ii)		Control mechanisms regarding fluctuations in demand and backlog	✓		
21.17	(i)		Internal quality assurance system for self-assessment	✓		
		(a)	for compliance with S&E Guidelines	✓		
		(b)	for channeling feedback to staff	✓		
	(ii)		System for measurement of data and reporting for continuous improvement	✓		
	(iii)		System for verifying the effectiveness of actions taken to correct deficient S&E work, eliminate the causes and prevent issues from recurring	✓		
21.19		(a)	Contact person helping identify best practice between Authorities	✓		
		(b)	Contact person fostering continual improvement	✓		
		(c)	Contact person providing for effective communication with other Authorities for feedback and evaluation	✓		
21.20	(i)	(a)	Appropriate system for handling complaints	✓		
		(b)	Appropriate system for taking preventive/corrective actions	✓		
		(c)	Appropriate system for offering feedback to users	✓		
	(ii)	(a)	A procedure for monitoring user satisfaction & perception	✓		
		(b)	A procedure for ensuring their legitimate needs and expectations is met	✓		
	(iii)		Clear and concise guidance and information on the search and examination ~~S&E~~ process for the user	✓		
			Indication where and how the Authority makes its quality objectives publicly available	✓		

Chapter 21 requirement				Extent of compliance		
				full	part	no
21.21		(a)	Established communication with the International Bureau ~~WIPO and designated and elected Offices~~	✓		
		(b)	Established communication with designated and elected Offices	✓		
21.22			QMS of Authority clearly described and documented	✓		
21.23		(a)	Material making up the reference of quality procedures and processes for staff and management has been prepared and distributed	✓		
		(b)	Media available to support the reference material	✓		
		(c)	Document control measures are taken	✓		
21.24			Items which should be documented in the reference of quality procedures and processes	✓		
	(i)		Quality policy of the Authority and commitment to QMS	✓		
	(ii)		Scope of QMS	✓		
	(iii)		Organizational structure and responsibilities	✓		
	(iv)		Documented processes carried out in the Authority	✓		
	(v)		Resources available to carry out processes and implementing the procedures	✓		
	(vi)		Description of the interaction between the processes and the procedures of the QMS.	✓		
21.25	(i)		Records of which documents are kept and where they are kept	✓		
	(ii)		Records of results of management review	✓		
	(iii)		Records about training, skills and experience of staff	✓		
	(iv)		Records of evidence of conformity of processes, resulting products and services in terms of quality standards	✓		
	(v)		Records of results of reviews of requirements relating to products	✓		
	(vi)		Records of the S&E process carried out on each application	✓		
	(vii)		Records of data allowing individual work to be tracked	✓		
	(viii)		Records of QMS audits	✓		
	(ix)		Records on actions taken re. non-conforming products	✓		
	(x)		Records on actions taken re. corrective actions	✓		
	(xi)		Records on actions taken re. preventive actions	✓		
	(xii)		Records referring to search process documentation	✓		
21.26	(i)		Recording of the databases consulted during search	✓		

Chapter 21 requirement				Extent of compliance		
				full	part	no
	(ii)		Recording of keywords, combination of words and truncations during search	✓		
	(iii)		Recording of the languages used during search	✓		
	(iv)		Recording of classes and combinations thereof consulted during search	✓		
	(v)		Recording of a listing of all search statements used in databases consulted		✓	
	(vi)		Records about limitation of search and its justification	✓		
	(vii)		Records about lack of clarity of the claims	✓		
	(viii)		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 the QMS is ensured through:

- Implementation of measures aimed at improving examination quality, optimizing application processing, and introducing new information technologies, as outlined in annual and long-term plans;
- Monitoring the implementation of planned measures by the Head of Rospatent;
- Regular assessment of FIPS performance results;
- Systematic recording and analysis of suggestions from Rospatent staff with subsequent development of quality improvement measures;
- Conducting preventive, ongoing, scheduled, and ad-hoc quality control of searches and examinations;
- Maintaining a systematic approach to recording user complaints and developing measures to prevent recurring issues.

The development of the QMS is supported by:

- Proposals for enhancing the Russian Federation's legal framework to ensure compliance with international standards;
- Ongoing activities for methodological support of search and examination procedures.

In 2020, the International Certification Centre assumed responsibility for coordinating the development, implementation, and improvement of the QMS in accordance with international standards.

In 2021, Rospatent initiated the certification process for international search and international preliminary examination procedures under PCT in accordance with ISO 9001:2015 requirements (see Section 21.10).

In January 2023, following a successful certification audit, Rospatent obtained a certificate confirming the application of its QMS in compliance with ISO 9001:2015 requirements for international search and international preliminary examination under PCT.

In 2024, a decision was made to expand the QMS scope to include Rospatent's functions as a Receiving Office under PCT (Order No. 197 of April 16, 2024).

In October 2024, the certification body conducted a second surveillance recertification audit of the PCT QMS for compliance with ISO 9001:2015 requirements. Based on the audit results, the auditor issued a report confirming the eligibility for both extending the certificate's validity period and expanding its scope. ~~The certification body's decision to reissue the certificate with an expanded scope is expected within the established timeframe.~~ Following the international certification body's decision, the certificate has been reissued with an expanded scope of certification.

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 regarding the importance of meeting treaty and regulatory requirements, including PCT requirements for maintaining the quality of international search and preliminary examination, as well as QMS requirements, is disseminated to staff through the following channels:

- Through reports, regulations, and orders issued by the Head of Rospatent and the Director of FIPS, available in both paper and electronic format via the "Code" network resource accessible to all staff;
- During operational meetings conducted by the Head of Rospatent, the Director of FIPS, and their Deputy Directors;
- At sessions of the Rospatent Quality Council.

Information concerning the results of examination quality inspections, new procedures, and other updates related to the activities of Rospatent and FIPS is distributed to division heads for further communication to staff members.

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 reviews are conducted on the instruction of the Head of Rospatent. Planned reviews of the completeness and quality of public service provision are carried out in accordance with the Administrative Regulations. These reviews are performed by the Department for the Provision of Public Services of Rospatent, the Quality Monitoring Center of FIPS, the International Patent Cooperation Division, and heads of examination departments. Based on the review results, reporting documents are submitted to the Head of Rospatent.

(b) QMS objectives and targets are revised during the planning of Rospatent's activities, particularly during the preparation of the Public Declaration of Tasks and Objectives of the Federal Service for Intellectual Property and the development of annual activity plans for Rospatent and FIPS. This revision is based on performance parameters from the previous year.

(c) Relevant information is communicated to staff through orders and instructions distributed to all divisions and published on the "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 QMS reviews may address both specific aspects of operations and the system as a whole (for example, to determine its compliance with Chapter 21 requirements). Such reviews are conducted based on instructions from the Head of Rospatent within the framework of other planned activities. Following each review, a report is prepared. Proposals for QMS improvements are systematically 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 promotes the systematic identification and management of risks and opportunities that may affect its QMS and the conformity of its international search and examination processes.

In 2021, the Office initiated work on certification of the international search and international preliminary examination processes under the PCT in accordance with the requirements of ISO 9001:2015. In this context, the following documents were approved:

- Quality Policy (Order No. 184 of May 5, 2021);
- Quality Guidelines for International Search and International Preliminary Examination Processes under the Patent Cooperation Treaty (Order No. 501 of November 26, 2021);
- Procedure for Internal Audit in relation to the processes of international search and international preliminary examination under the Patent Cooperation Treaty (Order No. 501 of November 26, 2021);
- Procedure for QMS Analysis by the FIPS leadership in relation to the processes of international search and international preliminary examination under the PCT (Order No. 501 of November 26, 2021);
- Quality Objectives Related to the Activities of the Center for International Cooperation (Order No. 501 of November 26, 2021).

In December 2021, internal audits of the main and supporting processes of international search and international preliminary examination under the PCT were conducted. Based on the results of these internal audits, an Action Plan was approved to address the identified findings and improve the QMS (Order No. 28 of January 24, 2022).

The forms of QMS documents and reports pertaining to the workflow for the processes of international search and international preliminary examination under the PCT were approved (Decree No. 18/23 of March 25, 2022).

Amendments were made to the following existing QMS documents (Order No. 177 of March 30, 2022):

- Quality Guidelines for International Search and International Preliminary Examination under the Patent Cooperation Treaty;
- Procedure for Internal Audit as applied to the processes of International Search and International Preliminary Examination under the Patent Cooperation Treaty;
- Procedure for QMS Analysis by the FIPS leadership as applied to the processes of International Search and International Preliminary Examination under the Patent Cooperation Treaty.
- Additionally, Quality Goals for 2022 for the PCT QMS and the Plan for their achievement were approved (Order No. 171 of March 28, 2022).

In November 2022, a certification audit was conducted by a third party. As a result, the QMS for the processes of international search and international preliminary examination under PCT was recognized as conforming to the requirements of ISO 9001:2015.

In January 2023, following the international certification body's review of the audit report, Rospatent obtained a Certificate of Conformity for the PCT QMS to the requirements of ISO 9001:2015, No. 20100223015602 dated January 20, 2023, and valid until January 19, 2026. The certification was carried out in accordance with established auditing and certification procedures. Consequently, the QMS is subject to regular surveillance audits by the international certification body.

The 2023 Quality Goals for the PCT QMS and the Plan for their achievement were approved by Order No. 227 of May 24, 2023.

In October 2023, to assess the effectiveness of the QMS, internal audits of the main and supporting processes of international search and international preliminary examination under PCT were conducted (Order 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. A positive decision was made to extend the validity of the Certificate of Conformity No. 20100223015602. The surveillance audit report is registered in the certification body's information database.

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

The forms of QMS documents and reports related to the examination of international applications, and the conducting of international search and international preliminary examination under the PCT in the international phase, were updated and approved (Order No. 29/23 of April 19, 2024).

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

In September 2024, to analyze the implementation of the plans for achieving quality goals and assess the compliance of the QMS with its internal documentation and the requirements of the ISO 9001:2015 standard, the PCT QMS Internal Audit Program was approved (Order No. 365 of August 20, 2024).

Based on the results of the subsequent internal audit, amendments were made to the PCT QMS Quality Guidelines regarding the activities of the Receiving Authority (Order No. 492 of November 7, 2024).

In October 2024, the certification body conducted the second surveillance recertification audit of the PCT QMS for compliance with the requirements of ISO 9001:2015. Based on the results, the auditor prepared a report with conclusions confirming the eligibility for extending the certificate's validity period and expanding the scope of certification. ~~The certification body's decision to reissue the certificate with an expanded scope is expected within the established timeframe.~~ Following the international certification body's decision, the certificate was successfully reissued with an expanded scope.

The 2025 Quality Goals for the PCT QMS and the Plan for their achievement, accounting for the expanded certification scope, were approved (Order No. 331 of July 30, 2025).

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 a following manner:

- Registering applicant complaints, particularly concerning the quality of the provided state service of granting a patent for an invention, including the completeness and quality of searches and the examination of invention applications;
- Conducting routine quality control of searches and documents sent to applicants, along with regular and random checks of the completeness and quality of the state service related to the grant of a patent for an invention;
- Analyzing the causes of violations, regulatory gaps, and methodological problems identified through the examination of complaints and inspections, and developing measures to prevent these risks;

- Recording and analyzing comments and suggestions from Rospatent staff, and developing measures to improve the patent search and examination processes;
- Monitoring FIPS's performance indicators;
- Implementing activities included in the Rospatent and FIPS annual and long-term plans aimed at improving the quality of search and examination of invention applications, optimizing processing methods, and introducing 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; and

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) Staff recruitment, personnel management, and workforce analysis for FIPS divisions are conducted by the Human Resources Division. FIPS maintains a sufficient number of qualified examiners to conduct searches and examinations, with a sufficient reserve of vacancies to adjust staffing levels according to fluctuations in workload and changes in application subject matter.

All examiners hold higher education degrees (some of them also hold postgraduate qualification, which is considered advantageous) and possess foreign language proficiency, primarily in English, sufficient for examination purposes.

International application search and examination are assigned to qualified IP examiners who have access to the PROMT ~~Professional 12.0~~ machine translation system and specialized dictionaries covering various technical fields and languages. The PROMT system is server-hosted and integrated into both the internal search system and the unified Rospatent search platform. Examiners utilize modern search systems and databases that enable comprehensive analytical processing of documents.

In 2024, the following personnel measures were implemented:

- Approximately 30% of the FIPS employees transitioned to remote work arrangements to enhance operational efficiency
- Continued optimization of compensation and bonus systems for examination division staff
- Implementation of effective contracts specifying job responsibilities, performance metrics, and compensation criteria for examination staff, in accordance with the Russian Government's program for institutional capacity building
- Establishment of a personnel reserve to enhance personnel policy effectiveness, improve staff qualifications, and identify promising employees within examination divisions
- Continuation of the FIPS internship program designed to attract new specialists to patent examination
- Ongoing professional development in IP through master's programs at leading educational institutions (RSAIP, Russian Presidential Academy of National Economy and Public Administration (RANEPA), and Griboyedov Institute of International Law and Economics (Griboyedov IILE)), supplemented by regular participation in WIPO training activities
- Launch of a dedicated Master's program in "Innovation" for FIPS employees

To enhance training quality, ~~T~~the FIPS Department of Higher Education expanded its teaching staff to ~~11~~13 members. In accordance with the FIPS Development Program for 2024-2028, the network of its regional offices continues to expand across the Russian Federation.

Concerning staffing levels, the total number of examiners reached ~~924~~ 1,022 by ~~2024~~ 2025, with ~~444~~ 406 examiners engaged in international search, international preliminary examination, and related activities.

The International Patent Cooperation Division oversees international search and preliminary examination work and conducts quality control of reports. The Division comprises ~~25~~ 24 staff members, including 10 specialists responsible for international search, preliminary examination, and quality control.

(ii) FIPS maintains adequate administrative and technical staff to ensure efficient performance of all 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, which deals with implementation and support of information systems and resources, and prepares proposals for the development of information technology architecture of FIPS. The Computer Center deals with operation of automated systems, maintenance of computer facilities and software systems, and providing access to information files. All examiners' workstations are computerized. Since 2008, the automated system of electronic workflow for PCT applications at the international phase (ELA PCT) has been in operation.

(iv) For carrying out searches, examiners have access to automated search tools which cover both the documents included in the PCT minimum documentation specified in the Regulations under the PCT and documents beyond it. Each examiner has unlimited access from their workstation to the internal PatSearch system, containing full texts of all patent documents of the USSR and Russia since 1924, patent documents of the members of the Commonwealth of Independent States (CIS), and files of patent documents from other countries and international organizations included in the PCT minimum documentation. Examiners also have access through PatSearch to the Scientific Electronic Library (eLibrary.ru), and can redirect queries to European Patent Office (EPO) Espacenet and the EMBL European Databank of genetic sequences.

Examiners have online access to updating search resources including websites of foreign patent offices, regional and international organizations (WIPO, EPO, USA, Japan, Republic of Korea, People's Republic of China, Germany, and others). They can access non-patent information websites related to medicine, pharmaceuticals, chemistry, and biotechnology. Since 2017, examiners have had access to India's TKDL search system containing traditional knowledge information. They also have access to reference websites, dictionaries and online translators from their workstations.

Besides freely accessible databases, in ~~2024~~ 2025 examiners obtained access to commercial databases including STN International. Under the "National Subscription" Project, FIPS obtained free access to QUESTEL-ORBIT, ~~Springer Nature Protocols and Methods, Springer Materials~~, Nature magazine electronic resources, ~~as well as electronic journals from the Russian Academy of Sciences~~, John Wiley & Sons publications, and journals from the Steklov Mathematical Institute of the Russian Academy of Science.

Examiners have access from their workstations to 19 scientific/technical periodicals and ~~7~~ 4 patent-related legal periodicals in electronic form. Trained patent searchers assist examiners with searches in commercial search systems. When necessary, automated search may be supplemented with traditional search using patent collections on paper or optical disks available at the All-Russian Patent and Technical Library collections. Through interlibrary subscription and electronic document delivery, examiners can obtain copies of non-patent documentation from 8 major Moscow libraries.

Examiners are informed of all changes in information search resources through new Guidelines for search in information resources, which are placed on the public segment of the intra-office computer network. Information letters about access to information files are distributed to examining divisions.

(v) Working procedures and their proper execution are detailed in instructions and guidelines approved by the Head of Rospatent and/or the Director of FIPS. These documents are distributed in paper form to all divisions and are also available electronically in the "Code" section of the Intranet, accessible to Rospatent and FIPS staff members.

International search and preliminary examination are conducted in accordance with the PCT International Search and Preliminary Examination Guidelines. The examination process also follows the Guidelines for Exercising Administrative Procedures and Actions in the Provision of Public Services for State Registration of Inventions and Grant of Patents for Inventions, which were developed in 2018 to provide methodological support for application processing. During the development of these Guidelines, the PCT International Search and Preliminary Examination Guidelines were taken into account, particularly regarding information search procedures.

All mentioned Guidelines, along with the list of approved Internet resources accessible from examiners' workstations, are published on the public segment of the intra-departmental 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 the FIPS Director in 2009. The following forms of training are utilized:

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

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

3. Internal training:

    - Training within the divisions in accordance with quarterly plans developed by the heads of each division. This training is targeted primarily at studying new regulatory documents and discussing and analyzing quality monitoring results.
    - Centralized training under specially developed programs for examiners and technical staff.
    - Regular training of the examiner staff in search skills is carried out by qualified FIPS specialists. Training on the International Patent Classification (IPC) and Cooperative Patent Classification (CPC) is also conducted.
    - Internal training plans are consolidated quarterly by the Scientific and Educational Centre (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

4. External Training and Exchange: Training based on the exchange of experience with other patent Offices, including participation in workshops conducted by leading examiners from other patent offices and organizations, such as the EPO Academy and the WIPO Academy.

5. Education at RSAIP (a subordinate body to Rospatent):

    - Education under programs of higher education in the fields of "Jurisprudence" and "Management"
    - Post-graduate studies

6. Specialized FIPS Programs were developed by its specialists and are inseparably linked to the working process. These programs target beginner examiners:

    - "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 theoretical lectures, these programs include practical exercises and business games organized in small groups based on examiners' requests. Highly qualified FIPS examiners (practicing trainers) are involved in the training. Teaching materials are developed by these practicing trainers based on real issues arising in examiners' work. During the training (3-4 months), besides the main theoretical part, an examiner examines real applications, which helps them acquire professional skills already at the education stage. In 2021, more than 100 beginner examiners completed these programs, including staff from the dynamically developing Siberian Centre of FIPS (Novosibirsk).

Experienced examiners continue their development through advanced distance training programs such as "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", and "Commercial and Regulatory Specificity of Circulation of Medicines in the Context of IP Rights Protection".

7. QMS-specific Training: As part of the measures to develop and implement a QMS meeting the requirements of ISO 9001:2015 in FIPS, two educational seminars were organized for the management and expert departments under the professional development program "International Standard ISO 9001:2015. QMS and Audits". 55 FIPS employees were trained under this program. From 2020 to 2024, more than 70 FIPS employees underwent training in QMS programs.

8. Language Training: Since 2020, the FIPS Scientific and Educational Centre (SEC) 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. 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) Resources are monitored through the continuous collection and analysis of statistical data from all FIPS divisions across reporting periods. This enables effective supervision and planning of procedures, including international search and international preliminary examination.

The required number of examiners is determined using internal labor standards to ensure effective and high-quality performance of activities.

The Division of International Classifications and Information Support for Patent Law Objects, in cooperation with examiners from various divisions, regularly monitors information resources across different fields of science and technology. This includes evaluating new information sources and providing examiners with either workstation access (for freely available resources) or access through special Search Rooms (for restricted resources). National documents are reclassified during IPC revisions, with amendments translated into Russian and corresponding Russian-language versions created.

Under the 2013 Agreement between Rospatent and EPO regarding the Cooperative Patent Classification, Rospatent has been using CPC alongside IPC as its internal classification system since 2016.

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 of FIPS performs the following functions:

- Records applications received for international search and preliminary examination, and prepares corresponding receipt notifications;
- Assigns applications to appropriate examining units with specified deadlines for report submission to the Division;
- Collects international search reports, declarations of non-establishment of international search reports, written opinions, and international preliminary examination reports from examining units, verifies these documents, and prepares notification packages and reporting documents for dispatch;
- Transmits all notifications and reports to the International Bureau of WIPO and applicants.

(i) Time-limit control is performed by both the heads of examining units and the International Patent Cooperation Division. The internal automated system ELA PCT, which contains international application data, enables monitoring of deadlines for preparing international search reports and written opinions.

(ii) Based on annual analysis of application distribution across various fields of science and technology (IPC headings), administrative redistribution of IPC headings among units is implemented when significant workload imbalances between examiners from different units are identified. Applications and assignments for international search and preliminary examination received by examining units are distributed by their leaders with consideration of individual 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) Rospatent has implemented the following quality assurance scheme for the preparation of international search and preliminary examination reports, consistent with the approved QMS documents for PCT processes (see section 21.10 of this Report):

The quality of search and examination reports is supervised by the leaders of examining units. International search reports, written opinions, and international preliminary examination reports (PCT reports) are verified by examiners of the International Patent Cooperation Division of FIPS. Identified issues in PCT reports are typically resolved through discussion between examiners of the examining unit and the Division. In case of disagreements, the PCT report together with the Division's formalized assessment outlining the identified issues is submitted to the leader of the respective examining unit for analysis and potential correction. When the leader of the examining unit disagrees with the Division's assessment, the final decision regarding necessary corrections to the PCT report is made by the supervisor of the examining unit.

(ii) The International Patent Cooperation Division's formal assessment of PCT report quality is compiled in accordance with the Regulations under the PCT and the PCT International Search and Preliminary Examination Guidelines, while also considering the approved QMS documents for PCT processes (see section 21.10). This assessment essentially constitutes a checklist verifying:

- Timeliness of submission
- Correct application classification using the current IPC version
- Alignment of search fields with the claimed subject matter and comprehensive coverage of the inventive concept and all claimed features
- Proper identification and characterization of relevant documents for each searched claim
- Correct determination of unity of invention
- Appropriate claim grouping by the examiner in cases of non-compliance with unity requirements
- Complete addressing of all claims (except those not searched) regarding novelty, inventive step, and industrial applicability
- Comprehensive presentation of all necessary observations
- Clarity of claims, description, and drawings, and proper basis of claims on the description

The Division maintains records using approved QMS document forms for PCT workflow processes (see section 21.10), analyzes this data to evaluate achievement of established QMS performance indicators and quality objectives, and monitors compliance with reporting document submission deadlines.

Based on the results, when necessary, proposals are developed for training or preparation of recommendations aimed at addressing deficiencies identified in PCT reports. These proposals are submitted for approval to the Head of the International Cooperation Center, the FIPS Deputy Director supervising the International Cooperation Center, and the FIPS Deputy Director overseeing the examining units.

6. COMMUNICATION

Inter-Authority communication:

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

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

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

(a) helping identify and disseminate best practice among Authorities;

(b) fostering continual improvement; and

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

(a), (b), (c)

Ms. Margarita AGARKOVA, Deputy Head, International Patent Cooperation Division, FIPS (amv20otd@rupto.ru) and

Ms. Elena SOROKINA, Deputy Head, Quality Monitoring Center/ Head, Division for General Matters of Public Services Provision (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 appeals (including complaints) from citizens and legal entities at Rospatent is conducted in accordance with the following documents, which establish the procedures and requirements for such consideration:

- Federal Law No. 59-FZ of May 2, 2006 "On the Procedure for Considering Appeals from Citizens of the Russian Federation" (as amended);
- Federal Law No. 210-FZ of July 27, 2010 "On the Organization of the Provision of State and Municipal Services" (as amended);
- Rules for Filing and Considering Complaints Against Decisions and Actions (Inaction) of Federal Executive Bodies and Their Officials, Federal State Civil Servants, and Officials of State Extra-Budgetary Funds of the Russian Federation, approved by Decree of the Government of the Russian Federation No. 840 of August 16, 2012 (as amended);
- Administrative Regulations for the Provision of the State Service for State Registration of an Invention and Grant of a Patent for an Invention, and Their Duplicates, approved by Order of Rospatent No. 163 of December 11, 2020, registered with the Ministry of Justice of the Russian Federation on February 15, 2021;
- Internal Instructions for Handling Appeals from Citizens and Legal Entities.

An applicant is entitled to file a complaint with Rospatent and/or its subordinate institution FIPS regarding violations of the state service provision procedure if they believe their rights and legitimate interests have been infringed.

A complaint about violations of the state service provision procedure is a request from an applicant or their legal representative to the body providing the state service, or to the official providing the state service, to restore or protect the infringed rights or legitimate interests of the applicant. A complaint shall be processed by an authorized official within 15 business days from the date of its registration.

Any individual may submit proposals or comments regarding Rospatent's activities in accordance with Federal Law No. 59-FZ of May 2, 2006. Appeals received by other state authorities of the Russian Federation on matters within Rospatent's jurisdiction are forwarded to the IP Office for the consideration.

The Division for General Matters of Public Services Provision is responsible for recording, analyzing, and summarizing the results of processing public complaints and other appeals, as well as preparing relevant outcome documents. Complaints and other requests received by Rospatent are registered, recorded, and statistically processed through an automated system.

Appeals received by the Head of Rospatent and Director of FIPS during personal meetings are subject to registration and subsequent consideration in the same manner as those received by mail.

Upon consideration of a complaint, the IP Office, as the service-providing authority, shall make one of the following decisions:

- Grant the complaint, which may include canceling the contested decision, correcting misprints and errors in documents issued during service provision, or refunding payments not stipulated by Russian regulatory legal acts;
- Deny the complaint.

A reasoned response regarding the outcome of the complaint consideration shall be communicated to the applicant in writing or, upon the applicant's request, in electronic form no later than the day following the decision date.

The results of complaint considerations are reported to the management of Rospatent and FIPS.

Typically, following complaint consideration, the Quality Monitoring Center prepares a position paper outlining the complaint's basis, assessment of their validity, evaluation of the lawfulness of actions (or inaction) by officials administering procedures related to service provision, and proposals for addressing identified violations and their causes. This position paper is forwarded to the relevant division and subdivision heads for review and appropriate action.

The overall situation regarding filed complaints is analyzed and utilized to assess the performance of FIPS divisions. The Quality Monitoring Center prepares quarterly and annual reports on complaint handling results, containing information on complaint causes, identified deficiencies, measures taken to address root causes, and complaint volume dynamics. This information is used in preparing the relevant section of Rospatent's annual activity report.

When deficiencies infringing upon the legitimate rights of applicants or patent holders are identified, measures are taken to restore these rights.

Preventive measures – actions aimed at eliminating the causes of potential deficiencies identified by applicants or patent holders – are systematically implemented. This typically involves analytical work and the selection of optimal measures, which may include developing technological processes, preparing clarifications on appropriate procedures, and other relevant actions.

Compliance with the established timeframes and thoroughness in processing citizens' appeals is monitored in accordance with the requirements outlined in the documents referenced in part (i) of this section.

Following the consideration of an appeal (including a complaint), a written response is sent to the individual who submitted it. If a complaint is upheld, comprehensive measures are taken to fully address the identified deficiencies.

(ii) Interested parties may submit comments, suggestions, and proposals regarding IP Office procedures through their appeals. These submissions are evaluated for their feasibility and relevance. If deemed advisable, a formal proposal is drafted for their integration into the Office's operations. Comments and suggestions are utilized by the relevant departments of Rospatent and subdivisions of the Quality Monitoring Center to prepare proposals for amending regulatory and methodological documents.

Feedback from interested persons on draft regulatory documents, published on the Federal Portal of Draft Regulatory Legal Acts (http://regulation.gov.ru) and the Rospatent website, is taken into account during the finalization of these drafts.

(iii) Information regarding the conduct of international search and preliminary examination is available on the official Rospatent website under the section "System for Filing International Applications under the PCT." This section is organized into the following subsections:

- PCT News
- Overview of the PCT
- Practical Guide for PCT Users
- International Patent Law
- Regulatory Documents and PCT Forms (including Russian translations of PCT normative documents)
- Methodological Materials and Recommendations developed by FIPS to assist Russian applicants
- Resources

In order to provide citizens and institutions with information, FIPS maintains a Unified Consulting and Inquiry Service comprising two units: a Consulting Unit and an Inquiry Unit, which provide information on matters within FIPS's competence.

The consulting unit provides free consultations on issues whose resolution does not require systematic analysis and/or comprehensive application of legal regulations in the field of legal protection of intellectual property and means of individualization (including inventions, utility models, industrial designs, trademarks and service marks, and appellations of origin). Consultations are provided orally by telephone, in person at the consulting center, and in writing via email.

The inquiry unit is equipped with a multi-channel public telephone line and provides citizens and institutions with general supplementary information, including telephone numbers, conditions and procedures for state service provision, as well as the status of application processing.

Another function of the Service is to analyze and systematize issues, identify the most frequently asked questions, and refer them through established procedures to competent examiners for preparing responses intended for publication and/or posting on Rospatent's official website.

Based on the Service's work results, the Rospatent and FIPS websites contain materials explaining various stages of obtaining legal protection for intellectual property, tailored to different levels of applicant preparedness:

- Section "For Newcomers"
- Section "FAQ"
- Section "Technology and Innovation Support Centers" (https://www.fips.ru/about/tspti-tsentr-podderzhki-tekhnologiy-i-innovatsii/index.php), including subsections "Cooperation with Russian regions" and "For small and medium enterprises on the protection and use of intellectual property"
- Section "Inventions and Utility Models"

The FIPS Consulting and Inquiry Service is equipped with an electronic data terminal allowing applicants to access information published on the official website and designed to help applicants familiarize themselves with state service procedures.

Annual conferences, seminars, and thematic round tables on intellectual property protection are regularly organized, enabling users to obtain information. Additionally, workshops and seminars

are held at various intellectual property exhibitions in which Rospatent participates, where users can also seek opinions on various matters.

The Public Declaration of Tasks and Objectives of Rospatent for ~~2024~~ 2025 is available on the official website (~~https://Rospatent.gov.ru/ru/about/openRospatent/publ-dec-2024~~ https://Rospatent.gov.ru/content/uploadfiles/1/public-dekl-2025.pdf).

Additionally, users are informed about quality-related goals and objectives at Rospatent's annual Scientific and Practical Conferences, various seminars, and round tables.

21.21 Communication with WIPO and designated and elected Offices:

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

Rospatent communicates with WIPO via email, PCT-EDI, and ePCT systems. ~~Rospatent typically does not communicate with designated and elected Offices by mail, fax, or email regarding matters related to international applications.~~

Since 2012, electronic document exchange between Rospatent, acting as Receiving Office (RO/RU), and the International Bureau of WIPO, and since 2014 between Rospatent, acting as International Search Authority (ISA/RU), and the International Bureau, has been conducted via PCT-EDI. The internal ELA PCT system enables the electronic preparation of RO/RU and ISA/RU document sets, which include various notifications, international search reports, written opinions, as well as requests and replacement sheets submitted by applicants, for transmission to the International Bureau.

Since October 2015, ISA/RU has utilized the eSearchCopy service. ~~In 2022, electronic application copies filed with twelve receiving offices were provided to ISA/RU for search by the International Bureau via the PCT-EDI system.~~

Since 2015, Rospatent, acting as International Preliminary Examining Authority (IPEA/RU) and Supplementary International Searching Authority (SISA/RU), has been receiving Demands and Supplementary Search Requests from the International Bureau via PCT-EDI. Since late 2015, IPEA/RU has used the ePCT system to download documents related to PCT Chapter II.

Information exchange is also facilitated through participation in the Meetings of International Authorities under the PCT. Meeting participants prepare reports highlighting issues of particular relevance to Rospatent, based on which action plans are developed to address these matters.

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.

Quality management matters are regulated by a set of documents. At present, there is no single comprehensive document. Requirements regarding the quality of administrative procedures related to the search and examination of applications are established by the Regulations.

Matters concerning search and examination are addressed in the Procedure for Information Search during Substantive Examination of Patent Applications and Reporting, adopted by Order No. 107 of the Ministry of Economic Development of the Russian Federation dated February 21, 2023, as well as in the Guidelines for Administrative Procedures and Actions in the Provision of Public Services for State Registration of Inventions and Grant of Patents, adopted by Order No. 236 of Rospatent dated December 27, 2018.

Application classification according to IPC and CPC is addressed in the IPC Guidelines and CPC Manual, which are updated in line with revisions to the corresponding WIPO and EPO documentation.

Procedures implemented within the QMS are described, in particular, in the following internal documents:

- Regulations on the Organization and Implementation of Quality Control, Analysis and Evaluation of Work at FIPS (Order of Rospatent No. 146 of December 20, 2002);
- Procedure for FIPS Divisions to Perform Work Related to Rospatent's Functions as International Searching Authority and International Preliminary Examining Authority under the Patent Cooperation Treaty (Order No. 135 of April 8, 2021);
- Procedure for Cooperation among FIPS Divisions in Performing Work Related to Various Types of Search and Examination under International Agreements (Order No. 536 of December 7, 2021); (see also sections 21.15(v) and 21.24);
- Quality Guidelines for International Search and International Preliminary Examination Processes under the Patent Cooperation Treaty (Order No. 177 of March 30, 2022, as amended by Order No. 492 of November 7, 2024);

- Internal Audit Procedure for International Search and International Preliminary Examination Processes under the Patent Cooperation Treaty (Order No. 177 of March 30, 2022);
- Procedure for QMS Analysis by FIPS Management in Relation to International Search and International Preliminary Examination Processes under the Patent Cooperation Treaty (Order No. 177 of March 30, 2022);
- Procedure for FIPS Units to Implement Work Related to Rospatent's Functions as a Receiving Office under the Patent Cooperation Treaty (Order No. 314 of July 17, 2025).

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's quality policy is reflected in the Public Declaration of Goals and Objectives of Rospatent for ~~2024~~ 2025, available at: ~~https://rospatent.gov.ru/ru/about/openrospatent/publ-dec-2024~~ https://rospatent.gov.ru/content/uploadfiles/1/public-dekl-2025.pdf

(ii) The documents referenced in section 21.23 of this Report specify their respective scopes of application.

(iii) The documents referenced in section 21.23 identify the organizational units responsible for executing work and define their respective competencies. Additionally, an internal structural regulation establishes the FIPS organizational framework, including provisions for each constituent division that delineate their objectives, functions, structure, and authority.

(iv)-(vi) The documentation enumerated in section 21.23 contains comprehensive information regarding:

- Procedures implemented by the Office during search and examination activities
- Available operational resources
- Protocols for interdepartmental coordination and collaboration

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 maintains a system for technical and administrative document storage.

(ii) Refer to section 21.08(a) of this Report.

(iii) Data regarding staff professional qualifications and career progression are stored electronically. Information on staff training and professional development is compiled quarterly and included in the Rospatent Annual Report.

(iv) Records concerning the quality of international searches and preliminary examinations are incorporated into formalized assessments stored electronically by the International Patent Cooperation Division of FIPS.

(v) When requirements for procedures and their implementation change (for example, due to regulatory amendments, new international treaties, evolving practices, or technical enhancements), internal documents are updated accordingly.

(vi) International search reports, written opinions, and international preliminary examination reports are retained in international application files for at least 10 years.

(vii) Data related to searches conducted for specific applications are preserved as search histories in the internal search database (see paragraph 21.26).

(viii) Based on QMS inspection results, reference documents, conclusions, or reports may be issued.

(ix), (x) and (xi) Decisions by the Head of Rospatent and Director of FIPS regarding measures to address identified deficiencies are formalized through their corresponding orders or instructions.

(xii) Documentation of the search process for PCT applications is maintained through search histories in the search database, with search results entered into the PCT forms used for compiling international search reports.

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 regulations that came into force on April 29, 2023, the search procedure is regulated by the following documents:

- Rules for the Preparation, Filing and Consideration of Documents Forming the Basis for Legally Significant Actions for the State Registration of Inventions (similar Rules have been issued for utility models);

- Procedure for Conducting an Information Search in Relation to a Claimed Invention During the Substantive Examination of an Application for the Grant of a Patent for an Invention and Submitting a Report Thereon;

- Procedure for Publishing an Information Search Report for a Claimed Invention;

- Procedure for Conducting a Preliminary Information Search in Relation to a Claimed Invention and Preliminary Assessment of Patentability, Submission of a Preliminary Information Search Report and an Opinion on the Results of the Preliminary Patentability Assessment for a Claimed Invention, Publication of a Preliminary Information Search Report for a Claimed Invention. This Procedure was developed due to amendments to the Code introduced by Federal Law No. 262-FZ. The preliminary information search and

preliminary assessment of patentability are performed at the applicant's initiative. 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 inventions and utility models, as well as concerning features and objects that are excluded from the search.

The Rules for the Preparation, Filing and Consideration of Documents Forming the Basis for Legally Significant Actions for the State Registration of Inventions and the Requirements for Application Documents for a Patent for an Invention were also amended by Order of the Ministry of Economic Development of the Russian Federation No. 610 of September 27, 2024, regarding the assessment of inventive step for claimed objects related to the use of a product or method for a specific purpose.

The Guidelines for the Execution of Administrative Procedures and Actions within the Framework of the Provision of the State Service for the State Registration of an Invention and Grant of a Patent for an Invention, Their Duplicates, and the Guidelines for the Execution of Administrative Procedures and Actions within the Framework of the Provision of the State Service for the State Registration of a Utility Model and Grant of a Patent for a Utility Model, Their Duplicates contain explanations regarding the determination of the search subject, field, and scope when conducting an information search. The Guidelines provide recommendations for preparing a search request and incorporating the concepts (keywords) used in this request into a search report.

Since 2011, 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 conducted in the PatSearch system as well as in the search systems of other providers. When using external databases, the recording of search results is made to the extent provided by the respective database.

The PatSearch system logs the search history, which reflects the search sessions conducted by an examiner. Furthermore, the PatSearch system enables the compilation of statistical reports on performed searches, which include the following data: databases used, examiner identification, number of search queries, and number of reviewed documents.

The unified search history form includes the following:

- Text of the query (a combination of search concepts and operations composing the query);
- Number of documents cited (according to the results of this query);
- Search arrays (information arrays in which the search for this query has been conducted);
- The number of documents reviewed (in relation to this query);
- Bibliography of the documents included in the final selection by the examiner.

The examiner who conducted the search has access to the aforementioned data (for example, for the purpose of reusing obtained search results in the case of similar or analogous applications). Additionally, for the purposes of selective control and resolution of disputed issues,

access to this data is provided to management staff as well as staff of the Quality Monitoring Center. A search history is used for monitoring the quality of the search.

The PatSearch information retrieval system's search history recording software allows for the export of a search report in MS Word format. Since 2017, PatSearch has provided the ability to export the bibliography of documents selected by examiners to the electronic internal document management system for its inclusion in the Search Report.

Search results are documented by completing the Search Report (Form PCT/ISA/210) in accordance with the requirements and details specified in the PCT International Search and Preliminary Examination Guidelines.

In addition to assessing novelty and inventive step, an examiner indicates the following in the International Search Report:

- Non-conformity with the unity requirement;
- Classification of subject matter (IPC indices);
- Field of search (IPC indices);
- List of databases used;
- Search limitations, if:
  - certain claims relate to subject matter that does not require an international search according to Rule 39 of the Regulations under the PCT;
  - certain claims are so unclear, even taking into account the description and drawings, that it is not possible to conduct a comprehensive search for them;
  - the requirement for unity of invention is not fulfilled and no additional fee has been paid for certain claims.

In addition to providing an opinion on whether the claimed invention is new, involves an inventive step, and is industrially applicable, the written opinion provides a substantiated explanation of the reasons for the search limitations. Furthermore, the written opinion may include observations regarding the clarity of the claims, the description, and the 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.

See sections 21.04, 21.06, 21.08, 21.09, 21.16 and 21.17 of this Report.

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]