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)

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

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

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

Abbreviations:

Rospatent – Federal Service for Intellectual Property, Patents and Trademarks
FIPS – Federal Institute of Industrial Property under Rospatent
RGIIS - Russian State Institute of Intellectual Property under Rospatent.
References to the legislation related to QMS besides Chapter 21 of the Guidelines.

The issues of granting of legal protection to the results of intellectual activity, in particular to the inventions, are provided for by the Part IV of the Civil Code of the Russian Federation (hereinafter referred to as the Code), put into effect from January 1, 2008.

The fulfillment by Rospatent of the state function concerning the granting of patents for inventions is provided for by the Administrative Regulations, adopted by the Order of the Ministry of Education and Science of the Russian Federation dated October 29, 2008, № 327, registered in the Ministry of Justice of the Russian Federation on February 20, 2009, № 13413 (hereinafter referred to as the Regulations).

The Regulations provide for the list of requirements related to search and examination of the applications including filed under the Patent Cooperation Treaty (PCT). The Regulations also provide for the order and timeframes of execution the administrative procedures, and the order and methods of the quality control.

The requests of the applicants, rightholders and other persons are considered in conformity with the Federal Law № 59-ФЗ dated from May 2, 2006.

1. LEADERSHIP AND POLICY

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

(a) The quality policy established by top management.

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

(c) An organisational 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 Strategy of Rospatent Development till 2015 approved by the Director General of Rospatent. The Director General of Rospatent is responsible for development of QMS and policy in this field.

(b), (c) Supervision of issues related to functioning and improvement of QMS is assigned to Mrs. Kiriy L.L, Deputy Director of Rospatent.

The organizational structure of QMS includes the following supervising divisions:

1) The Quality Service dealing with the common issues of the quality control. The management of Quality Service is assigned to Mrs. Alexeeva O.L., Deputy Director of FIPS.

2) Department “Chamber of Patent Disputes” dealing with appeals against the decisions of Rospatent. The management is assigned to Mr. Zhuravlev A.L, Deputy Director of FIPS.

3) International Patent Cooperation Division dealing with quality control of the international search reports, written opinions and international preliminary examination reports. The Head of the Devison is Mrs. Popova L.I. The control over the division work is assigned to Mr. Zhuravlev A.L., Deputy Director of FIPS.

See the scheme on organizational structure of QMS bellow.
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.*

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

(a) the effectiveness of the QMS; and

(b) that the process of continual improvement progresses.

(a), (b) The effectiveness of QMS is ensured by:

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

Development of QMS is provided by:

- Proposals on improvement of the Russian Federation legal system for the purpose of compliance with the international standards.
  - Activities on methodical support of search and examination.

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 on importance of contractual and normative requirements, including requirements of the PCT concerning the maintenance of quality of international search and international preliminary examination, as well as requirements of QMS is brought to the notice of the staff:

- by regulations and orders of the Director General of Rospatent and the Director of FIPS on paper and in electronic form (on the Intranet);
  - during operative meetings of the Director General of Rospatent, the Director of FIPS and the Head of Quality Service;
  - during the sessions of the Methodical Council of FIPS established with a view of solving problems of examination of applications.
The information on results of inspections of examination quality, new procedures, other information concerning the activity of Rospatent and FIPS is sent to the heads of divisions for informing staff and using in its work.

21.08 Indicate how and when top management of the Authority or delegated officers:

(a) conducts management reviews and ensures the availability of appropriate resources;

(b) reviews quality objectives; and

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

(a) Administrative inspections are carried out by orders of the Director General of Rospatent. The Director General of Rospatent determines the volume and terms of inspections. The inspection is carried out by the Quality Service. Report prepared according to the results of inspection is represented to the Director General of Rospatent.

(b) The targets of QMS are revised in the course of planning of Rospatent activity (preparation of long-term Strategy of Development of Rospatent and plans of Rospatent and FIPS activity for the next year based on the parameters of activity of the Office for previous year).

(c) The corresponding information is brought to the staff by issue of orders and instructions, which are communicated to the divisions and posted on Intranet.

21.09 Indicate whether top management or delegated officers of the Authority perform an internal review of the QMS in accordance with paragraphs 21.25-21.28:

(a) at least once per year (cf. paragraph 21.25);

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

(i) to determine the extent to which the QMS is based on Chapter 21 (cf. paragraphs 21.25, 21.27(a));

(ii) to determine the extent to which Search and Examination work complies with PCT Guidelines (cf. paragraphs 21.25, 21.27(a));

(c) in an objective and transparent way (cf. paragraph 21.25);

(d) using input including information according to paragraphs 21.27 (b)-(f);

(e) recording the results (cf. paragraph 21.28).

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

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

21.10 Explanatory note: The granting of ISEA status means that the Authority has demonstrated it has the infrastructure and resources to support the search and examination process. Chapter 21 calls for assurance that the Authority can continually support this process while accommodating changes in workload and meeting QMS requirements. The responses to Sections 21.11 to 21.14, below, should provide this assurance.

21.11 Human resources:

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

(i) sufficient to deal with the inflow of work;

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

(iii) 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.

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

(i) at a level to support the technically qualified staff and facilitate the search and examination process;

(ii) for the documentation of records.

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

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

All examiners must have a higher education (post graduated degree is a great asset) and foreign language skills, especially English. Carrying out search and examination of the international applications is assigned to the most qualified examiners.

The examiners have access to the machine translation system (PROMT Professional 7.0) and specialized dictionaries on various subject matters.

(b) (i, ii) There are quality personnel for fulfillment of administrative and technological procedures.
21.12 Material resources:

(a) Describe the infrastructure in place to ensure that

(i) appropriate equipment and facilities such as IT hardware and software to support the search and examination process are provided and maintained;

(ii) 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.

(b) Describe how instructions

(i) to help staff understand and adhere to the quality criteria and standards, and

(ii) to follow work procedures accurately and consistently

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

(i) The infrastructure of IT is provided by:

- The Department for Automated System Development dealing with designing and elaboration of program applications, computer information technology and support of information systems;

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

All examiners workplaces are computerized.

The automated system of electronic workflow of the PCT applications «Electronic Library of the PCT Applications » («ELA PCT») is developed and put into operation.

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

Each examiner has an unlimited access from their workstation to internal search system PatSearch. Full texts of all patent documents of the USSR and Russia since 1924, patent documents of the CIS States, and also files of patent documents of foreign countries and the international organizations which documentation are included into PCT minimum are loaded into the system. The database DWPI has been included in PatSearch in 2009.

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

The sites containing non-patent information, relating to medicine, pharmaceutics, chemistry, and biotechnology (for example, database MEDLINE, databases on biotechnology of national library on medicine of the USA and the European Bioinformatics Institute) are accessible to the examiners.

Besides the above freely accessible databases, the examiners have access to commercial databases in special Search Rooms (databases provided by the network STN International, covering both patent and non-patent literature; abstract database «RZ VINITI»; database of patent documents of Japan in English PATOLIS-e). Qualified examiners assist in carrying out searches in the specified commercial search systems.
Within the bilateral cooperation with the European Patent Office, the examiners have limited access to internal search system EPOQUENet.

When it is necessary, the automated search can be added by traditional search in patent collections on paper or optical disks.

The examiners are informed on all changes occurring in information search resources, including the Guidelines for search in information resources.

The information letters are communicated to examination division both in paper and in electronic form via Intranet.

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

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

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

21.13 Training resources:

Describe the training and development infrastructure and program which ensures that all staff involved in the search and examination process:

(i) acquire and maintain the necessary experience and skills; and

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

(i), (ii)

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

There are the following forms of training:

1. Individual training, in particular, with use of computer technologies (distant training, including provided by the programs of the WIPO Academy, training with use of the computer integrated training systems intended for self-training and self-examination by means of testing).

2. Tutorship - training aimed at assimilation of the profession. Results of this training are supervised directly by the tutor in the process of internal quality review of the documents prepared by new employee.

3. Internal training

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

3.2. Centralized training under the specially developed programs for the examiners and technical staff.
4. Training based on exchange of experience with other patent offices - traineeship, participation in workshops conducted by the leading experts of the patent offices and organizations, including the EPO Academy and the WIPO Academy;

5. Education in RGIIS.

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

5.2. Training under the programs of the first and second higher education in the fields “Jurisprudence” and “Economics and Management”.

5.3. Post-graduate course in RGIIS.

6. Regular training of examiners related to search skills carried out by qualified personnel.

The Manual related to the International Patent Classification (training examples) has been developed.

In 2009 for the purposes of improvement of professional skill in the field of quality management, a project related to probation in the Quality Service of the examiners of the divisions of FIPS, included in a promotion list as the heads and deputes heads of divisions was launched. During the probation the specialists of the Quality Service are training the examiners in the field of the standard documents regulating the FIPS QMS and quality management principles, in particular on the basis of results of quality control as well as the results of consideration of the complains filed to Rospatent and FIPS.

21.14 Oversight over resources:

Describe the system in place for continuously monitoring and identifying the resources required:

(a) to deal with demand; and

(b) comply with the quality standards for search and examination

(a), (b) The Plan and Production Division permanently collects and analyses the statistics of search and examination reports, which allows supervising and planning procedures, including the international search and international preliminary examination. The necessary number of examiners is calculated on the basis of the internal labor standards for maintenance of effective and qualitative fulfillment of the activity.

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

As a result of the annual review of distribution of the applications received by the examination divisions of FIPS according to the International Patent Classification, in
case of misbalance of workload of the divisions, such distribution is under correction. In 2010 the reorganization of the examination divisions of FIPS took place.

3. Management of administrative workload

| 21.15 | 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:
| (a) | Effective control mechanisms regarding timely issue of search and examination reports to a quality standard as set by the respective Authority; and
| (b) | Appropriate control mechanisms regarding fluctuations in demand and backlog management.

The International Patent Cooperation Division:

- Records search and examination requests, prepares the notifications of their receipt, complements application files, classifies subject matter for each application and defines the examination division for execution.

- Prepares an assignment to appropriate examination division with indication of deadline for submission of documents to International Patent Cooperation Division

- Takes and checks the international search reports prepared in examination divisions, the written opinions and the international examination reports.

- Issues above mentioned documents and sends them to WIPO and the customers

  a) Control of internal time limits is exercised both by the examination division (where search and examination are carried out) and the International Patent Cooperation Division. The International Patent Cooperation Division when forwarding the assignment to the examination division stipulates in compliance with the requirements of the Regulations as to the dates for preparation of search or examination report and controls thereof. Each application is examined by the expert of the International Patent Cooperation Division who is responsible for consideration and control of the deadlines.

  b) Applications and assignments for carrying out the international search and international preliminary examination received by the examination division are distributed by the administration of the examination division.

  Rospatent is working on upgrading the special automated system, which includes data on the PCT applications being considered at the international phase.
4. Quality assurance

21.16 The following are required quality assurance measures for timely issue of search and examination reports of a quality standard in accordance with the Guidelines. Indicate how the following are implemented:

(a) An internal quality assurance system for self assessment, involving verification, validation and monitoring of searches and examination work:
   (i) for compliance with these Search and Examination Guidelines;
   (ii) for channelling feedback to staff.

(b) 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.

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

(a)

(i) The following quality assurance scheme of drawing up international search and examination reports is provided in the Office. The quality of search and examination reports is supervised by the administration of examination divisions. Then search and examination reports are checked by the International Patent Cooperation Division.

(ii) The defects in search and examination reports, as a rule, are corrected after discussing thereof between the expert of the International Patent Cooperation Division and examiner of the examination division. In case of disagreements, the documents prepared by examiner and the expert’s opinion about their quality (the formalized conclusion) are transferred to the examination division for further correction.

(b) With respect to each application the expert of the International Patent Cooperation Division draws up the expert’s opinion related to the search and examination reports, which includes some criteria for evaluation of conformities or non-conformities to requirements of the International Search and Preliminary Examination Guidelines and internal standards, such as:

- meeting of deadlines;
- if the application is properly classified using current version of IPC;
- if field of search and search strategy are appropriate to claimed subject matter and encompass the inventive concept and claimed features;
- if relevant documents are properly identified and characterized with respect to each claim subjected to search;
- if unity of invention is determined correct;
- where the application was not considered as complying with the requirements of unity, groupings of claims set forth by examiner were proper;
- if all claims (excluding claims that are not subjected to search) are addressed with regard to novelty, inventive step and industrial applicability;
- if all appropriate opinions are set forth;
observation of clarity of the claims, the description and the drawings, and whether the claims are fully supported by the description are appropriate.

The International Patent Cooperation Division makes proposals, in particular, concerning the expediency of training or recommendations for avoiding such defects in search and examination reports, and forwards the proposals for consideration by the respective supervisor of the Division – the Deputy Director of FIPS.

5. Communication

21.17 Inter-Authority communication:

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.

Liudmila Popova, Head of the International Patent Cooperation Division, e-mail: otd29ch@rupto.ru
Petrunina Tatiana, Principal State Expert on Intellectual Property, Legal Support Division of Quality Service, e-mail: otd1846@rupto.ru

21.18 Communication and guidance to users:

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

(a) An appropriate system for
   (i) handling complaints and making corrections;
   (ii) taking corrective and/or preventative action where appropriate; and
   (iii) offering feedback to users.

(b) A procedure for:
   (i) monitoring user satisfaction and perception; and
   (ii) for ensuring their legitimate needs and expectations are met.

(c) 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.

(d) An indication of where and how the Authority makes its quality objectives publicly available for the users.

(a) (i) Consideration of the appeals (including complaints) of the citizens and legal entities filed before Rospatent is carried out in accordance with the following documents, which describe the procedure and requirements for such consideration:
   - Administrative Regulation of the Execution by the Federal Service for Intellectual Property, Patents and Trademarks of State function according to which Rospatent “Shall organize reception of citizens, ensure timely and complete consideration of citizens’ oral

- Internal instruction for the citizens and legal entities appeals handling.

Any person in his/her appeal may submit proposals or opinions concerning activities of Rospatent, including complaints. Appeals filed to other State Authorities of the Russian Federation involving matters of Rospatent jurisdiction are forwarded to Rospatent for consideration.

Functions of accounting, analyzing and summarizing the results of public appeals handling in Rospatent and working out the outcome documents are entrusted to the Accounting and Request Analysis Division of Quality Service.

Registration, accounting and statistical processing of written requests received by Rospatent, is realized by automated system.

Requests, including complaints, addressed to the administration of Rospatent and FIPS are registered by the Quality Service, and after input to a computer-aided database are transferred for consideration to a duly authorized subdivision. During the registration of a complaint a registration card containing relevant information on the complaint is prepared. Consideration of a complaint and time limit for a response thereto are taken under control.

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

As a rule, according to the results of a complaint consideration in the Quality Service, a summary is prepared, which contains the grounds of the complaint, evaluates lawfulness of subdivision staff actions and validity of the complaint, Quality Service proposals for overcoming the situation if the applicant's rights are recognized to be infringed. The summary is forwarded for familiarization and preparation of adequate proposals to the head of division which comprises said subdivision, and also to the head of the subdivision. The measures are taken to remove drawbacks, the causes of the drawback appearance are identified and analyzed, proposals on the elimination of the revealed causes and prevention of similar shortcomings are elaborated. If needed, a check for evaluating the situation on this matter is carried out in subdivisions executing the similar work.

A person who filed a complaint is informed on the results of its consideration and on the corresponding measures taken.

The results of complaints handling are reported to the Head of Rospatent on weekly operational meetings, where they are discussed, and measures aimed at excluding the cases of recurrence of the violations are elaborated (carrying out trainings, the issue of informative, regulatory and methodological documents, the adoption of administrative measures, etc.).

Information on reasonable complaints, their motives and the measures taken based on the results of their consideration, are quarterly placed on the official site of in the Internet.

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

The Quality Service quarterly and by the results of the year prepares a report on the outcome of complaints handling, which contains information concerning the reasons for complaints, revealed drawbacks, taken measures and actions aimed the elimination of the causes of drawbacks and the dynamics of complaints inflow.
(ii) In case of identifying drawbacks, which infringe the legitimate user rights, the measures for the restoration of these legitimate rights are taken. Preventative measures, namely, actions aimed at the elimination of the causes of potential drawbacks identified by users, are accepted without fail. As a rule, the analytical work and the selection of optimal measures are carried out, including the development of technological processes, the preparation of clarifications on the appropriate actions, etc.

The timely and full consideration of citizens appeals are monitored in accordance with requirements of the Administrative Regulation referred to in paragraph (i).

(iii) Subsequent to the results of an appeal consideration, a written response is sent to a person who has filed the appeal.

(b) (i), (ii) The users submit their comments, suggestions and proposals regarding the office work in their appeals. The consideration of these comments, suggestions and proposals includes the assessment from the standpoint of their advisability.

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

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

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

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

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

With the view to improve of the consultative and reference information furnishing activity providing to citizens the Advisory and Reference Service is created in Rospatent. In this service users receive free consultations on various issues. Additional task is the analysis and systematization of problems, as well as the selection of the most frequently asked questions and their transfer in the prescribed order to the competent experts for the preparation of a response for the publication and/or posting on the official Rospatent website.
Every year conferences, seminars, topical round tables on the issues in the field of intellectual property protection are organized, that allow users to obtain information. Additionally, workshops and seminars are held at various exhibitions relating to the intellectual property in which Rospatent takes part, where users can also take opinion on various issues.

d) The Strategy of Rospatent Development until 2015 is available on the official Rospatent website, where aims and objectives in the field of quality in various areas of Rospatent activity are represented (http://www.rupto.ru/about/sod/str_rf_2015.html).

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

21.19 Communication with WIPO and designated and elected Offices:

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

Rospatent and FIPS communicate with WIPO via mail, fax and email and substantially do not communicate with designated and elected Offices. Rospatent as the designated Office orders from WIPO published documents from the Communication on Request (COR) website. Rospatent as receiving Office and International Searching and Examination Authority has started exchanging of the documents with WIPO via PCT-EDI.

Besides, informational exchange is carried out through the participation in the Meetings of International Authorities under the PCT. As a result of such participation a report is prepared, where the received information, which is of interest for Rospatent and FIPS, is set forth and a plan of action is prepared if necessary.

6. Documentation

21.20 Explanatory note: The QMS of the Authority needs to be clearly described and implemented so that all processes in the Authority and the resulting products and services can be monitored, controlled, and checked for conformity. This is done in the documents that make up the Quality Manual of the Authority (see paragraph 21.21).

(Note: This point is informative. No response is required by the template to paragraph 21.20)

21.21 The documents that make up the Quality Manual serve to document the procedures and processes affecting the quality of work, such as classification, search, examination and related administrative work. In particular, the Quality Manual indicates where to find instructions on the procedures to be followed.

For the purposes of this report indicate:

(a) the documents making up a Quality Manual that have been prepared and distributed;
(b) the media on which it is supported (e.g. Internal Publication, Internet, Intranet); and
(c) document control measures taken e.g. version numbering, access to latest version.

The issues of the quality management are regulated by a set of documents, which form a Quality Manual in Rospatent. At present there is no single document.
The issues of quality of the administrative procedures related to search and examination of applications are established by the Regulations.

The issues concerning the search and examination are considered in the Information search guidelines and in Recommendations on the issues of examination of applications, adopted by the Orders of the Director General of Rospatent.

The procedures, which are implemented within the scope of the QMS, are described also in the Regulations on organization and implementation of control, analysis and evaluation of the quality of execution of works in FIPS, which discloses

- the order of FIPS divisions interaction in the course of the execution of search and examination;
- the order of the organization and control of the execution of orders of Rospatent and FIPS’ Heads.

(See also paragraphs 21.12(b), 21(22))

<table>
<thead>
<tr>
<th>21.22</th>
<th>Indicate whether the documents making up the Quality Manual include the following:</th>
</tr>
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<tbody>
<tr>
<td>(a)</td>
<td>The quality policy of the Authority including a clear statement of commitment to the QMS from top management;</td>
</tr>
<tr>
<td>(b)</td>
<td>The scope of the QMS, including details of and justification for any exclusions;</td>
</tr>
<tr>
<td>(c)</td>
<td>The organizational structure of the Authority and the responsibilities of each of its departments;</td>
</tr>
<tr>
<td>(d)</td>
<td>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;</td>
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<tr>
<td>(e)</td>
<td>The resources available for carrying out the processes and implementing the procedures; and</td>
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<tr>
<td>(f)</td>
<td>A description of the interaction between the processes and the procedures of the QMS.</td>
</tr>
</tbody>
</table>

(a) The Office policy in the field of quality is reflected in Development Strategy of Rospatent.

(b) The documents mentioned in paragraph 21.21 indicate the field of application thereof.

(c) The documents mentioned in paragraph 21.21 indicate the subdivisions entrusted with the execution of works and their competence. Besides, there is an internal agency-level document, establishing FIPS structure as well as provisions on each division forming part of the structure, which determines goals, functions, structure and rights of each division.

(d) - (f) The list and the description of procedures implemented by the Office in the course of carrying out the search and examination, available resources and interaction between the divisions are contained in the documents listed in paragraph 21.21.
### 21.23 Indicate which types of records the Authority maintains, such as:

(a) a definition of which documents are kept and where they are kept;
(b) results of management review;
(c) training, skills and experience of personnel;
(d) evidence of conformity of processes, resulting products and services in terms of quality standards;
(e) results of reviews of requirements relating to products;
(f) the search and examination processes carried out on each application;
(g) data allowing individual work to be tracked and traced;
(h) records of QMS audits;
(i) actions taken re. non-conforming products, e.g. examples of corrections;
(j) actions taken re. corrective action;
(k) actions taken re. preventative action; and
(l) search process documentation as set out in Section 7.

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

(b) See paragraph 21.08 (a).

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

The data relating to the training and professional skill of the staff are prepared quarterly in the form of notes and are included in the Rospatent Annual Report.

(d) The records concerning the quality of documents drawn up based on the results of international search and international preliminary examination are included into a formalized report which is stored in the International Patent Cooperation Division.

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

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

(g) The data relating to the search are stored by keeping the search history in a search database as indicated in paragraph 21.24.

(h) Based on the results of the inspection of the QMS a note, opinion or report may be issued.

(i), (j), (k) The decisions of the Director General of Rospatent, Director of FIPS concerning the measures which should be taken in connection with the drawbacks revealed, are fixed in a form of correspondent record in the orders, instructions of the Director General of Rospatent or Director of FIPS.
The documenting of the search process and search results for PCT applications is made by filling the corresponding PCT form and by keeping the search history in the search database.

7. Search process documentation

21.24 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:

(i) limitation of search and its justification
(ii) lack of clarity of the claims; and
(iii) lack of unity.

Search process documentation is carried out by filling in the Search Report (Form PCT/ISA/210) in accordance with the requirements and details specified by PCT International Search and Preliminary Examination Guidelines.

In the Search Report the examiners among other things indicate:

- unity / lack of unity of the invention;
- which claims have been taken into account;
- classification of subject matter (by IPC indexes);
- search scope (by IPC indexes);
- list of used databases;
- limitation of search, if:
  - claims relate to the subject matter of application which doesn’t require search according to Rule 39;
  - claims are so unclear even taking into account the description and drawings, that it is not possible to make an comprehensive search on them;
  - the requirement of unity of invention is not fulfilled and no additional fee has been paid for some claims.
Explanation for search limitation is given in the written opinion. Besides, even when search is not limited, the written opinion may include comments regarding clarity of claims, of the description and drawings and whether claims are fully supported by the description.

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

The PatSearch search system makes it possible to:

- fix automatically the history of search requests, namely:
  - a number of found documents
  - a text of search request
  - a search mode
- to store for unlimited period:
  - a request in examiner’s workbook for further use;
  - the list of documents according to any request;
  - separate documents, which the examiner considers relevant.

Should the keywords included into the request are specified in Russian, there is a possibility to automatically translate the selected terms.

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

The examiner who has carried out the search has the access to the aforementioned data (for example, for the purpose of recurrent use of obtained search results in case of similar or analogous applications). Besides, for the purposes of selective control and the solution of disputable issues, the access for these data is provided for the direct and superior leaders of this examiner, as well as for the staff of the Quality Service.

8. Internal review

21.25 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.

21.26-21.28 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.
9. Arrangements for Authorities to Report to the MIA

21.29 There are two stages in the reporting arrangements. The document up to this point relates to the initial report called for by paragraph 21.29. It will be supplemented annually by further reports in accordance with paragraph 21.30.

[End of document]