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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 United States Patent and Trademark Office (USPTO)

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.

Chapter 21 of the PCT International Search and Examination Guidelines (the Guidelines) sets forth an overview of the Quality Management System each International Authority is expected to implement with respect to its processing of International Applications. The Guidelines set forth criteria with respect to resources, administration, quality assurance, feedback arrangements, communication and guidance to users, and internal review procedures. The overall implementation of the Quality Initiative for International Applications within the USPTO is discussed below with reference to specific sections of Chapter 21 of the Guidelines.

Normative Reference for QMS

As described in more detail below, the USPTO's Office of Patent Quality Assurance is primarily responsible for the review of national and international searches and examinations for compliance with the applicable laws, regulations, Treaties, etc. The Office of Patent Quality Assurance (OPQA) obtained ISO 9001:2008 certification of its Quality Management System (QMS) in December, 2011.

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 OPQA QMS is fully documented, and all documentation, including the Quality Policy, roles and names of those responsible for the QMS and an organizational chart, are available internally via SharePoint.

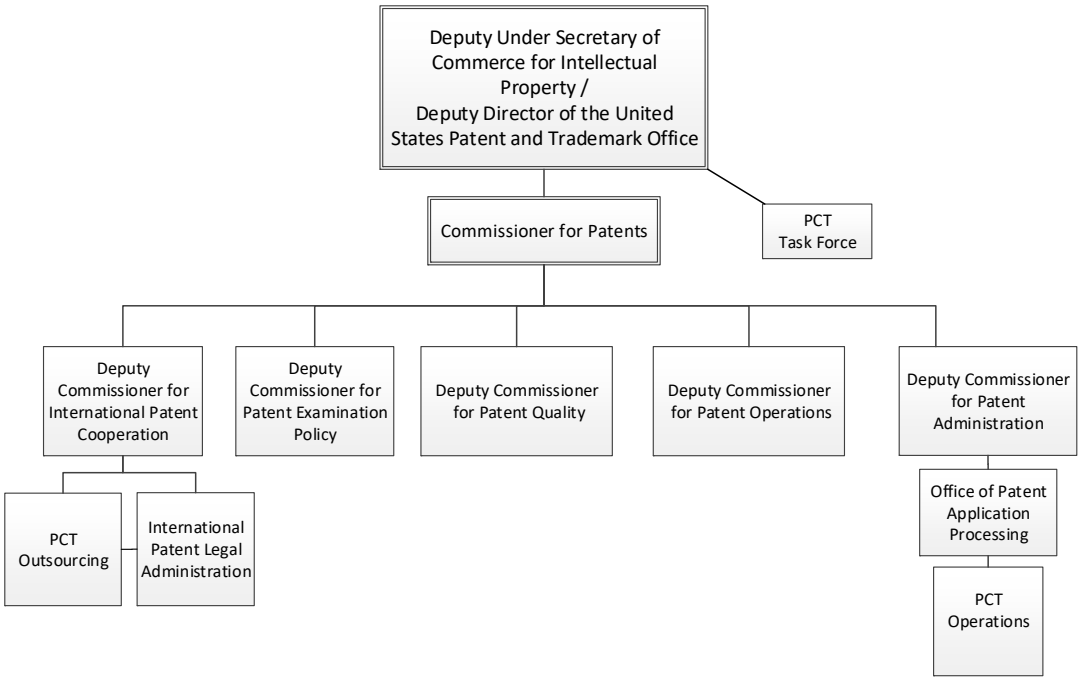
In fiscal year 2015, the USPTO launched the Enhanced Patent Quality Initiative (EPQI) Quality Metrics Program, comprising three metric categories: Product Indicators, Process Indicators, and Perception Indicators. All quality measures are available on the USPTO's Quality Metrics website. Quality performance targets and achievements are available in the annual USPTO Performance and Accountability Report. Specific quality requirements for USPTO PCT outsourcing contractors (for USPTO ISA work) are available via contract solicitation notices or Request for Proposals (RFP).

(b) The responsibility for oversight of examination quality for international applications at the USPTO operates under the overall administrative and policy direction of the Commissioner for Patents. Under the Commissioner for Patents, management of overall PCT operations is divided between the Deputy Commissioner for Patent Operations (DCPO), the Deputy Commissioner for Patent Examination Policy (DCPEP), the Deputy Commissioner for Patent Administration (DCPA), the Deputy Commissioner for International Patent Cooperation (DCIPC), and the Deputy Commissioner for Patent Quality (DCPQ). The DCPO, the DCPEP, the DCPA, the DCIPC, and the DCPQ are responsible for specific aspects of the USPTO activities as Receiving Office, International Searching Authority (ISA), and International Preliminary Examining Authority (IPEA) under the Patent Cooperation Treaty. The DCPO, the DCPEP, the DCPA, and the DCPQ are therefore collectively involved in the operation and/or implementation of an overall quality assurance system designed to ensure compliance with Chapter 21 of the Guidelines. Within the DCPQ organization, the USPTO has an Office of Patent Quality Assurance which is responsible for the quality assessment of all USPTO search and examination work products, both national and international. For PCT work performed by contractors, there is an additional layer of quality review and control which is under the direction of the DCPO and DCIPC. Contracting Officer Technical Representatives (COTRs), under the DCIPC, are responsible for contract compliance, including quality review, control and feedback.

Ultimately, responsibility for the USPTO's Quality Management System lies with the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office. The Director of the USPTO receives briefings on the USPTO's quality initiatives on at least a quarterly basis and more frequently when circumstances dictate.

Additionally, with specific regard to PCT quality, the Director of the USPTO has established a PCT Task Force which is tasked with reviewing all aspects of PCT processing at the USPTO, including the Quality Management System, in an effort to identify areas where improvements can be made. The Task Force is comprised of staff from all areas of the USPTO that are involved, either directly or indirectly, with the processing of PCT applications. In addition to reviewing USPTO PCT processing, the Task Force also considers what changes, if any, should be made to the PCT system as a whole and has also solicited advice from our users on areas where improvements can be made in USPTO PCT processing and to the PCT system as a whole.

(c)



Further USPTO organizational information can be found on the USPTO's web site at:

https://www.uspto.gov/about-us/organizational-offices/office-commissioner-patents and

https://www.uspto.gov/about-us/organizational-offices

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

Chapter 21 requirement				Extent of compliance		
				full	part	no
21.04		(a)	Quality policy available	✓		
		(b)	Identified roles and names for QMS responsibility	✓		
		(c)	Organizational chart available	✓		
21.05			Established compatibility of QMS with Chapter 21	✓		
21.06		(a)	Mechanisms to ensure effectiveness of the QMS	✓		
		(b)	Control of the continual improvement process	✓		
21.07		(a)	Communication of management about this standard to staff	✓		
		(b)	The PCT Guidelines are in line with the Authority's QMS	✓		
21.08		(a)	Management reviews take place	✓		
		(b)	Quality objectives are reviewed	✓		
		(c)	Communication of quality objectives to the relevant staff at the Authority	✓		
21.09		(a)	Performance of a yearly internal review of the QMS in/to	✓		
		(b)	determine the extent to which the QMS is aligned with Chapter 21	✓		
			determine the extent to which S&E complies with PCT Guidelines	✓		
		(c)	an objective and transparent way	✓		
		(d)	using input incl. information according paragraph 21.24		✓	
		(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	✓		

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

Chapter 21 requirement				Extent of compliance		
				full	part	no
	(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 are met	✓		
	(iii)		Clear and concise guidance on the S&E process for the user	✓		
			Indication where and how the Authority makes its quality objectives publicly available	✓		
21.21			Established communication with WIPO and designated and elected Offices	✓		
21.22			QMS of Authority clearly described and documented	✓		
21.23		(a)	Material making up the reference of quality procedures and processes for staff and management has been prepared and distributed	✓		
		(b)	Media available to support the reference material	✓		
		(c)	Document control measures are taken	✓		
21.24			Items which should be documented in the reference of quality procedures and processes	✓		
	(i)		Quality policy of the Authority and commitment to QMS	✓		
	(ii)		Scope of QMS	✓		
	(iii)		Organizational structure and responsibilities	✓		
	(iv)		the documented processes are carried out in the Authority	✓		
	(v)		Resources available to carry out processes and implementing the procedures	✓		
	(vi)		a description of the interaction between the processes and the procedures of the QMS.	✓		
21.25	(i)		Records which documents are kept and where they are kept	✓		

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

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

(a) the effectiveness of the QMS; and

(b) that the process of continual improvement progresses.

(a)-(b) The management of the Office of Patent Quality Assurance monitors the effectiveness of the QMS and ensures that the process of continual improvement progresses. Additionally,

upper management, including the Director and the Commissioner for Patents, reviews throughout the year the level of quality achievement as reflected by the USPTO's EPQI quality metrics. Upper management sets annual targets that are communicated internally and made publically available. With specific regard to our ISA work products, a number of measures are used to determine the effectiveness of the QMS and to ensure continual improvement of the QMS and overall quality. One of those measures is an internal re-use study which compares the work of our Chapter I contractors to that of a USPTO examiner in the national phase.

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) The importance of compliance with applicable standards is communicated to USPTO staff through the quality requirements in their performance appraisal plans and to our PCT Chapter I contractors through the terms and conditions of their contracts.

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)-(c) The management of the Office of Patent Quality Assurance ensures that management reviews are conducted consistent with the requirements of ISO 9001:2008; that the Quality Objectives are regularly reviewed to assess their continued suitability; to evaluate performance relative to the Quality Objectives; and that the Quality Objectives and Quality Policy are communicated throughout the organization.

Top management or delegated officers at the USPTO are continually evaluating appropriate resources, quality objectives, and ensuring that objectives are communicated throughout the Office. Quality objectives are communicated and monitored as described above in 21.04 and 21.07. The monitoring of resources is not only reviewed by top management but is posted for external review on the Patents Dashboard of the USPTO Data Visualization Center (https://www.uspto.gov/dashboards/patents/main.dashxml).

21.09 Indicate whether top management or delegated officers of the Authority perform an internal review of the QMS in accordance with paragraphs 21.27-21.30:

(a) at least once per year (cf. paragraph 21.27);

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

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

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

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

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

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

(a)-(e) The management of the Office of Patent Quality Assurance ensures that management reviews as well as internal and external audits of the QMS are performed at least annually in order to ensure continued compliance of its QMS with the requirements of ISO 9001:2008. OPQA implements a quality assurance system to ensure that PCT work complies with PCT Guidelines.
USPTO recently launched the Enhanced Patent Quality Initiative (EPQI) Quality Metrics Program in fiscal year 2015. The scores/measures of the quality metrics and the individual components of the metrics are posted on-line.
https://www.uspto.gov/patent/patent-quality
https://www.uspto.gov/patent/initiatives/quality-metrics-1

With specific regard to the USPTO's PCT Chapter I contractors, a proposed QMS is established at the time of posting of a request for proposal (RFP) and finalized when contracts are awarded. The QMS for each PCT Chapter I contractor includes, *inter alia*, quality review, feedback, training, and specific implications for not meeting prescribed targets for quality and timeliness. Each contractor's QMS is modified with action plan(s) whenever prescribed targets for quality and/or timeliness fall outside of the contractual compliance rate.

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.

Yes, top USPTO management promotes practices to ensure the risks and opportunities that can affect the QMS and the conformity of international search and examination are addressed. See section 21.13, below.

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).

(i) Any issues potentially affecting the ability of the USPTO to achieve its intended results of the QMS are raised via quality feedback cycles through the management structure of the DCPO, the DCPEP, the DCPA, and the DCPQ, as they are all collectively involved in the operation and/or implementation of an overall quality assurance system designed to ensure compliance with Chapter 21 of the Guidelines (see section 21.04, above). The needs and expectations of interested parties are obtained through various outreach and public and private feedback mechanisms, one of which - the PCT Help Desk – receives calls from applicants, their representatives, and inventors as well as email inquiries from the International Bureau. This help desk is administered by the International Patent Legal Administration (IPLA), under the DCIPC. Additional internal quality feedback is provided by trainers, examiners, and supervisory examiners, to management staff.

Referring to 21.04, the USPTO uses the OPQA to assess the quality of all USPTO search and examination work products, both national and international. For PCT work performed by contractors, there is an additional layer of quality review and control which is under the direction of the DCPO and DCIPC. COTRs, under the DCIPC, are responsible for contract compliance, including quality review, control and feedback.

(ii)-(iii) Risks and opportunities related to the performance of the QMS are assessed and distributed across the various divisions (DCPO, DCPEP, DCPA, and DCPQ) that collectively implement and operate the PCT. Performances of each division are largely monitored by quality goals at a high level and individual quality goals in staff performance appraisal plans (see 21.07). Identification of risks and opportunities to mitigate and thereby improve quality of work products are fed back through management channels and the appropriate training or

remedy can be enacted. The PCT Chapter I outsourcing contract allows the USPTO to structure perceived risks to quality and timeliness of Chapter I work products by adjusting the volume of work assigned to a given contractor, thereby creating opportunity to reward contractors that meet the set quality and timeliness goals. Quality of PCT Chapter II work products, generated by USPTO patent examiners in the patent corps, are mitigated by requiring a senior-level examiner to review the work products before issuance.

(iv) The quality and timeliness of each contractor is continuously monitored for compliance with the requirements set forth in the contract. Volume of work may be adjusted when deemed appropriate to mitigate any perceived risk to quality and timeliness. Each contractor's QMS is modified with action plan(s) whenever prescribed targets for quality and/or timeliness fall outside of the contractual compliance rate. Based on quality trends, the PCT Chapter I contractors are provided training in areas in which the COTRs identify as areas of quality concern.

(v) Contractor work is continuously monitored for compliance with the requirements set forth in the contract. Volume of work may be adjusted when deemed appropriate to mitigate any perceived risk to quality and timeliness Work products issued by the patent corps are continually reviewed for quality by OPQA.

3. RESOURCES

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

Human resources:

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

sufficient to deal with the inflow of work;

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

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

is maintained and adapted to changes in workload.

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

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

for the documentation of records.

(i)-(ii) The Office of the DCPO continuously monitors staff resources in an attempt to ensure that search and examination of international applications can be accomplished in a timely manner. The decision to outsource PCT Chapter I work is an example of the USPTO adapting to workload needs and ensuring that the staff has the technical qualifications to perform the work. As discussed in 21.08 above, the staffing levels and workload models are made publically available.

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)-(iv) The Office of the Chief Information Officer (OCIO) and Office of Patent Information Management (OPIM) maintain search systems and technical information sources and ensures that PCT minimum documentation requirements are met and also manages the provision of information technology and automation equipment and facilities to ensure effective handling of national and international applications at all stages of search and examination.

(v) The International Patent Legal Administration (IPLA), under the DCIPC, is responsible for advising on, and assisting in, the updating of the USPTO's Manual of Patent Examining Procedure (MPEP) with respect to PCT matters and regularly reviews and revises the MPEP to reflect the ongoing PCT rule changes related to the efforts of the PCT Working Group. IPLA additionally updates training materials and provides training when there are changes in practice. These training materials are available to all USPTO employees via the USPTO's intranet.

Training resources:

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

acquire and maintain the necessary experience and skills; and

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

(vi) The DCPO currently maintains systems to train staff on the processing of ISA and IPEA reports. Under the DCPA is the Office of Patent Cooperation Treaty Operations (PCT Operations). PCT Operations reviews applications for compliance with the Treaty, Regulations, and Administrative Instructions, assigns international filing dates, and assures payment of appropriate fees. The IPLA, which operates under the DCIPC, is responsible for developing and providing training to the Patent Examining Corps' professional and technical support staffs. All new patent examiners receive PCT-specific training as part of the curriculum in the USPTO's Patent Training Academy. These courses are also offered as refreshers for experienced examiners. Monthly training courses are also provided on performing preliminary examination and preparing the associated forms for PCT Chapter II examination. All of the above-mentioned training programs are also made available to USPTO staff on the USPTO's intranet.
Based on quality trends, the PCT Chapter I contractors are provided training in areas in which the COTRs identify as areas of quality concern. For example, the following training modules were prepared and given to the PCT Chapter I contractors: search strategy for electrical, mechanical and chemical/biotechnologies, claim interpretation, unity of invention, and classification.

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) The oversight of resources to deal with demand and comply with quality standards is discussed in detail above in 21.04, 21.08 and 21.15.

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.

(i)-(ii) The majority of PCT administration responsibilities are handled by PCT Operations. These responsibilities include processing all International Applications for which the USPTO serves as the ISA, processing Demands for International Preliminary Examination, mailing of notices and reports, and other administrative duties. PCT Operations contributes to the ability of the USPTO to monitor timeliness and pendency of PCT search and examination by maintaining systems for tracking application movement and workflow. In addition to the work performed by PCT Operations, the office of the DCPO continuously monitors workload fluctuations and makes adjustments in an attempt to ensure that search and examination of international applications can be accomplished in a timely manner and maintains systems to monitor the timely issuance of search and examination reports. Finally, IPLA operates the PCT Help Desk, which handles customer complaints and provides customers with assistance on a wide variety of PCT matters.

5. QUALITY ASSURANCE

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

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

for compliance with these Search and Examination Guidelines;

for channeling feedback to staff.

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

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

(i) The Office of Patent Quality Assurance (OPQA), under the DCPQ, has primary responsibility for the development and implementation of an effective internal quality assurance program. Preliminary development of the framework for the PCT Quality Review Program began in FY04.

In the initial study, OPQA selected a random sample of International Applications and reviewed them against ten search report and written opinion criteria as noted below:

1. The application is properly classified using the current version of the IPC.
2. Field of search and search strategy are appropriate to claimed subject matter and encompass the inventive concept and claimed features.
3. Relevant documents are properly identified and characterized with respect to each claim subjected to search (e.g., “X”, “Y”, “A”, etc. with respect to claims…).
4. Where the international application was not considered as complying with the requirement of unity of invention, determination of lack of unity was appropriate.
5. Where the international application was not considered as complying with the requirement of unity of invention, groupings of claims set forth by the examiner were proper.
6. All claims (excluding claims that are not subjected to search) are addressed with regard to novelty, inventive step (nonobviousness), and industrial applicability.
7. All appropriate opinions are set forth.
8. No inappropriate opinions are set forth.
9. Observations raised in Box No. VIII are appropriate.
10. Opinions and observations are explained clearly using language appropriate to examination under the Patent Cooperation Treaty.

This preliminary stage of review was intended to solidify the framework for a more intensive review process, namely to:

- Evaluate the resource requirements needed per reviewed application;
- Evaluate the reliability and effectiveness of the evaluation instrument;
- Establish sufficient sampling parameters; and
- Identify sources of potential bias and misinterpretation.

(ii) Based on the results of the initial study, the USPTO greatly expanded the sampling of applications and implemented an expanded and more-defined evaluation instrument. OPQA employed a sampling design that ensures 95% confidence in review findings. The evaluation instrument covers the areas of overall search, the search report, and the written opinion. The review instrument was expanded largely to be able to identify specific improvement strategies. Reviewers assess the applicability and appropriateness of each item as well as provide comments specific to each area of review.

In 2010, the USPTO renegotiated the agreements with its contract searchers to include stricter quality standards. The stricter standards correspond more closely to the quality review standards to which the USPTO examining corps is held and additionally require that the most relevant art document be cited on the International Search Report. The renegotiated quality standards should help to insure that the quality of the international work products produced by the USPTO’s contract searchers is the same as that of its examiners.

(iii) Additionally, in fiscal year 2015, the USPTO adopted new procedures for measuring the quality of patent examination, known as the Enhanced Patent Quality Initiative (EPQI), which further expanded the previous procedures (the Patent Quality Composite) for measurement of examination quality. This new initiative is designed to ensure the USPTO continues issuing high-quality patents well into the future. EPQI is composed of 3 total factors, which are as follows:

1. Product Indicators, which include metrics on the correctness and clarity of our work products. We formulate these metrics using data from reviews conducted by the Office of Patent Quality Assurance using a Master Review Form.
2. Process Indicators, which assist in tracking the efficiency and consistency of internal processes. Our current focus is on analyzing reopening of prosecution and rework of Office actions as well as improving consistency of decision making. (See

https://www.uspto.gov/patent/initiatives/quality-metrics-1)

3. Perception Indicators, which use both internal and external stakeholder surveys to solicit information that can be used for root cause analysis and to validate/verify the other metrics.

Reports setting forth quality review findings are distributed on a regular basis to the DCPEP, DCPO, DCPQ, and DCIPC for use in the identification of areas in need of quality improvement.

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)-(c) Michael Neas
Deputy Director
International Patent Legal Administration, USPTO
Michael.neas@uspto.gov (v) 571-272-3289

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)-(iii) IPLA develops and provides training on a regular basis to users of the PCT system, including patent attorneys and agents, legal administrators, legal secretaries and other members of the patent community. Additionally, IPLA operates the PCT Help desk, which provides customers with assistance on a wide variety of PCT matters. In the most recent fiscal year (October 2018 through September 2019) the PCT Help Desk handled more than 22,000 calls, as well as approximately 1272 emails and 58 fax submissions, from PCT users. Finally, IPLA provides information, forms, and updates on the PCT home page of the USPTO Internet

site. Feedback and complaints received by the PCT Help Desk are monitored and used to develop training. Additionally, the PCT Help Desk staff routes application specific issues for correction when appropriate. Refer to 21.04 and 21.08 for how quality objectives are made publically available for our users.

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.

Personnel from IPLA are in regular contact with officials from PCT Operations at WIPO and are available to officials from the other Authorities and the designated/elected Offices for the purposes of receiving feedback on quality 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.

The USPTO's procedures and processes affecting the quality of work, such as classification, search, examination, and related administrative work, are set forth in numerous documents that are readily available to our examiners and, to a slightly lesser extent, to the public at large. The procedures and processes which affect quality are set forth, in general, via the USPTO's internet web site (www.uspto.gov) and its internal intranet system and, in particular, in the U.S. Patent Laws (United States Code Title 35), the U.S. Consolidated Patent Rules (Title 37 – Code of Federal Regulations Patents, Trademarks, and Copyrights), the aforementioned USPTO Manual of Patent Examining Procedure, the Patent Cooperation Treaty, the Regulations under the PCT, the PCT Administrative Instructions, the PCT International Search and Preliminary Examination Guidelines, the aforementioned quality metrics document, and the USPTO's PCT training materials.

(a) U.S. Patent Laws (United States Code Title 35), the U.S. Consolidated Patent Rules (Title 37 – Code of Federal Regulations Patents, Trademarks, and Copyrights), the aforementioned USPTO Manual of Patent Examining Procedure, the Patent Cooperation Treaty, the Regulations under the PCT, the PCT Administrative Instructions, the PCT International Search and Preliminary Examination Guidelines, the aforementioned quality metrics document, and the USPTO's PCT training materials.

(b) The USPTO's internet Web site and its internal intranet system.

(c) Version numbering or dates are recorded/applied to all the above-mentioned documents.

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.

As set forth above in 21.21, the documents comprising the USPTO's Quality Manual are set forth in numerous documents but, the Quality Manual effectively includes each of items (a) – (f) listed above.

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

(i) a definition of which documents are kept and where they are kept;

(ii) results of management review;

(iii) training, skills and experience of personnel;

(iv) evidence of conformity of processes, resulting products and services in terms of quality standards;

(v) results of reviews of requirements relating to products;

(vi) the search and examination processes carried out on each application;

(vii) data allowing individual work to be tracked and traced;

(viii) records of QMS audits;

(ix) actions taken re. non-conforming products, e.g. examples of corrections;

(x) actions taken re. corrective action;

(xi) actions taken re. preventative action; and

(xii) search process documentation as set out in Section 7.

(i)-(xi) The Office of Patent Quality Assurance maintains these items as part of their QMS.

(xii) The USPTO creates a search history document for each application, which is made of record in the application file. Additionally, the search history document is mailed to applicant with the ISR/WO.

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.

(a) The USPTO records, in each international application in which it performs the search and/or examination, the following search process documentation, as appropriate:

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

(b)-(c) The USPTO generally does not include this information in its search history documents. However, any lack of clarity in the claims or lack of unity is documented in the opinion or report.

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.

The reliability of the aforementioned review instrument is continuously monitored to ensure that conclusions made from the data gathered through the PCT Quality Review Program are accurate and valid. A final report is prepared at the end of the Fiscal Year that provides the information necessary to evaluate and adjust training and quality improvement programs so as to ensure attainment and maintenance of high quality levels. Finally, as information is gathered and analyzed from the search and examination report review program, the Office will develop and provide supplemental training to improve areas of weakness.

10. ARRANGEMENTS FOR AUTHORITIES TO REPORT TO THE MIA

21.31 There are two stages in the reporting arrangements outlined in Chapter 21: the initial report called for by paragraph 21.31(a), and supplementary annual reports in accordance with paragraph 21.31(b). At the second informal meeting of the Quality Subgroup in Canberra on February 6 and 7, 2012, the Subgroup recommended that, instead of submitting full reports every five years and cumulative updates in the intervening years, Authorities should submit each report in the form of a full report, making the differences from the previous year's report clear, for example using "track changes" or other form of highlighting. The template for the supplementary annual reports is therefore no longer used.

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