

## **PATENT COOPERATION TREATY (PCT)**

### **Common Quality Framework for International Search and Preliminary Examination**

#### **INITIAL REPORT ON QUALITY MANAGEMENT SYSTEMS**

*prepared by SPANISH PATENT AND TRADEMARK OFFICE*

*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*

The SPTO has a Quality Management System certified according to ISO 9001:2008. The scope of this System is PCT procedure, Technological Watch procedures, Industrial Design, National trademarks and commercial names; in the near future other main processes of the office will be included in the scope.

The SPTO QMS is compliant with EQS except for point 5.2, 9 and first part of point 10, although there are different actions being made that will allow us to be fully compliant by the end of 2010.

## 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) SPTO Quality policy is defined within the parameters established by ISO 9001:2008 standard.

The directives that emanate from this Policy can be summarized in the following principles of performance:

1. Offering a legal and prescribed service in accordance with the specifications and requirements set by the relevant regulations and legislation, as much for the users as for the own Office.
2. Managing the processes by means of control, planning systems and permanent self-evaluation to guarantee the fulfillment of the acquired commitments and to anticipate and resolve possible service incidences.
3. Developing a participative management to promote the personnel abilities and that those will be used for the benefit of the Office, for reaching the maximum degree of staff motivation and collaboration, fomenting their professionalism, competition, qualification and culture.
4. Involving all Organization personnel in the objective benefits, promoting the participative management and the application of suitable quality management practices.
5. Providing systems with which to maintain an effective and suitable communication with users, to analyze its expectations, to evaluate its satisfaction, to take care of its claims and to offer an excellent treatment to obtain its total satisfaction.
6. Formulating ways of collaboration and commitment with our suppliers and contractors within the quality scope.
7. Establishing the continuous improvement as a priority of the management, by measuring, analyzing and interpreting the results of the processes and maintaining permanent communication with users, personnel and suppliers as sources to detect possible improvements in the quality of given services.

These principles serve as a frame for the establishment of specific objectives of quality that periodically are evaluated and reviewed by the Management Committee of the Organization.

The SPTO assures that this policy is reviewed periodically and is communicated and understood by all the people who participate in key processes, trying that everyone feels completely identified with it.

b) The QMS responsibilities at the SPTO are organized in two levels: an independent body responsible for quality managed by a Quality Advisor, reporting directly on the Director General and to the Quality Committee and the Quality Assessor of each Department who reports to the Director of Department and the correspondent Quality Management Groups.

c) The bodies and individuals responsible for the QMS are described at the Quality Manual. The update version of the Quality Manual is available at Inc@web application.

*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.*

[Sample table, to be amended as necessary]

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 throughout the Authority	✓		
21.09	(a)	Performance of a yearly internal review of the QMS in/to	✓		
	(b)	(i) determine the extent to which the QMS is based on Chapter 21	✓		

Chapter 21 requirement			Extent of compliance		
			full	part	no
		(ii) determine the extent to which S&E complies with PCT Guidelines	✓		
	(c)	an objective and transparent way	✓		
	(d)	using input incl. information according paragraph 21.17	✓		
	(e)	recording the results	✓		
21.10		Assurance to monitor and adapt to actual workload	✓		
21.11	(a)	Infrastructure in place to ensure that a quantity of staff	✓		
		(i) sufficient to deal with the inflow of work	✓		
		(ii) which maintains tech. qualifications to S&E in all technical fields	✓		
		(iii) which maintains the language facilities to understand languages according to Rule 34	✓		
	(b)	Infrastructure to provide a quantity of skilled administrative staff	✓		
		(i) at a level to support the technically qualified staff	✓		
		(ii) for the documentation records	✓		
21.12	(a)	(i) Ensuring appropriate equipment to carry out S&E	✓		
		(ii) Ensuring documentation accord. to Rule 34	✓		
	(b)	(i) Instructions to help staff understand and act accord. the quality criteria and standards	✓		
		(ii) Instructions to follow work procedures accurately and they are kept up-to-date.	✓		
21.13		(i) L&D program to ensure and maintain necessary skills in S&E	✓		
		(ii) L&D program to ensure awareness of staff to comply with the quality criteria and standards.	✓		
21.14	(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	✓		
21.15	(a)	Control mechanisms to ensure timely issue of S&E reports	✓		
	(b)	Control mech. regarding fluctuations in demand and backlog	✓		
21.16	(a)	Internal quality assurance system for self assessment	✓		
		(i) for compliance with S&E Guidelines	✓		

Chapter 21 requirement			Extent of compliance		
			full	part	no
		(ii) for channelling feedback to staff	✓		
	(b)	A system for measurement of data and reporting for continuous improvement	✓		
	(c)	System for verifying the effectiveness of actions taken to correct deficient S&E work	✓		
21.17	(a)	Contact person helping identify best practice between Authorities	✓		
	(b)	Contact person fostering continual improvement	✓		
	(c)	Contact person providing for effective comm. with other Authorities for feedback and evaluation	✓		
21.18	(a)	(i) Appropriate system for handling complaints	✓		
		(ii) Appropriate system for taking preventive/corrective actions	✓		
		(i) Appropriate system for offering feedback to users	✓		
	(b)	(i) A procedure for monitoring user satisfaction & perception	✓		
		(ii) A procedure for ensuring their legitimate needs and expectations are met	✓		
	(c)	Clear and concise guidance on the S&E process for the user	✓		
	(d)	Indication where and how the Authority makes its quality objectives publicly available	✓		
21.19		Established comm. with WIPO and desig. + elected offices	✓		
21.20		QMS of Authority clearly described (e.g. Quality Manual)	✓		
21.21	(a)	Documents making up the Quality Manual have been prepared and distributed	✓		
	(b)	Media available to support the Quality Manual	✓		
	(c)	Document control measures are taken	✓		
21.22	(a)	Quality policy of the Authority and commitment to QMS	✓		
	(b)	Scope of QMS	✓		
	(c)	Organizational structure and responsibilities	✓		
	(d)	the documented processes are carried out in the Authority	✓		
	(e)	Resources available to carry out processes	✓		
	(f)	a description of the interaction between the processes and the procedures of the QMS.	✓		

Chapter 21 requirement			Extent of compliance		
			full	part	no
21.23	(a)	Records which documents are kept and where they are kept	✓		
	(b)	Records of results of management review	✓		
	(c)	Records about training, skills and experience of staff	✓		
	(d)	Evidence of conformity of processes	✓		
	(e)	Results of reviews of requirements relating to products	✓		
	(f)	Records of the S&E process carried out on each application	✓		
	(g)	Record of data allowing individual work to be tracked	✓		
	(h)	Record of QMS audits	✓		
	(i)	Records on actions taken re. non-conforming products	✓		
	(j)	Records on actions taken re. corrective actions	✓		
	(k)	Records on actions taken re. preventive actions	✓		
	(l)	Records referring to search process documentation	✓		
21.24	(a)	(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	✓		
	(b)	Records about other information relevant to the search	✓		
	(c)	(i) Records about limitation of search and its justification	✓		
		(ii) Records about lack of clarity of the claims	✓		
		(iii) Records about lack of unity	✓		
21.25		Report on its own internal review processes			
21.26- 21.28		Additional information on further inputs to its internal reviews	✓		
21.29		Initial report called for by paragraph 21.19	✓		

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.

The QMS responsibilities at the SPTO are organized in two levels: an independent body responsible for quality at SPTO managed by a Quality Advisor, reporting directly on the Director General and to the Quality Committee and the Quality Assessor of each Department who reports to the Director of Department and the correspondent Quality Management Groups.

The Patent Department of SPTO has a *Quality Management Group* which plays a central role in the Quality Management System. The Quality Management Group is formed by all the Heads of the Operative Units, both administrative and technical, the Director of the Patent Department and the Quality Assessor of the Patent Department.

The main tasks of this group are:

- To ensure compliance with the Quality Policy
- To promote actions to achieve the Quality objectives and evaluate their effectiveness
- To Track and to analyze the results of quality indicators and taken necessary action as a result of this analysis.
- To support the implementation of the QMS and evaluate its effectiveness
- To analyze nonconformity reports and initiating corrective or preventative actions when necessary.
- To determine the effectiveness of corrective and preventative actions.
- To analyze results applicant satisfaction through surveys and claims and and taken necessary action when necessary

The *Quality Committee of the SPTO* is chaired by the Director General. Directors of all the departments of the SPTO are also members of the *Quality Committee*: General Secretary, Patents and Technological Information, Trademarks and International Relationship Department and the Quality Advisor of the SPTO. The main functions of the Committee are:

1. To approve the executive Report prepared by the Quality Management Groups reported by the Director of each department.
2. To define the general strategy for Quality in the Office.
3. To provide coordination among the different departments.
4. To provide financial and human resources to the Quality activities

*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.*

Heads of units have regular meetings with the examiners and administrative staff to inform of the evolution of their work, in those meetings the information about treaty and regulatory requirements are disseminated, also about quality standards and quality system.

The Technical Advisor of the Patent Department sends regularly information to all the staff about all the important issues as the evolution of indicators, new procedures or whatever information is relevant for the work of the Patent Department staff.

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

- (a) conducts management reviews and ensures the availability of appropriate resources;*
- (b) reviews quality objectives; and*
- (c) ensures that the quality objectives are communicated and understood throughout the respective Authority.*

See point 21.09

*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).*

Management review is held every twelve months by the Quality Committee. Also there is follow-up meeting every six months.



Previous to this review, the Quality Management Group of each department has a review meeting to study and prepare the information that each department is going to expose in the Quality Committee.

The agenda for review meetings is:

1. Follow-up actions from previous management reviews.
2. Evaluation of continuing suitability, adequacy and effectiveness of the Quality System and Quality Policy.
3. Non Conformities, Corrective and Preventative actions
4. Customer Information: Satisfaction Survey and Complains
5. Quality objectives evolution
6. Quality indicators evolution
7. Quality Control results
8. Follow up of Audit Plan
9. Internal and External audit reports review
10. Training plan follow-up. Evaluation of the effectiveness of the training actions taken
11. Monitoring of supplier evaluations
12. Review of the of the infrastructure and work environment
13. Identification of necessary resources.

With all this information the Quality Committee meets and reviews:

- Actions approved in previous meetings
- Possible changes related to QMS.
- Adecuation of Quality Policy.
- Results of audits, internal and external.
- Information related to Client Satisfaction
- Suppliers
- Training planning

And finally, decides which improving actions and budget for Resources and Infrastructure are necessary

The minutes of these two meetings are accessible to all the staff of the Department through our documentation management tool, Inc@web. Also quality objectives and their follow ups, as well as, indicators are also record on this application, this way we assure that staff involved in QMS have access to this information.

Every three months the QMG holds follow-up meetings, the agenda of those meetings is:

1. Monitoring actions approved on previous meetings.
2. Monitoring Non Conformities, Corrective and Preventative actions
3. Monitoring Customer Information: Satisfaction Survey and Complains
4. Monitoring Quality objectives evolution
5. Monitoring Quality indicators evolution
6. Monitoring results of Quality controls on issued reports
7. Monitoring actions related to Internal and External audit reports.
8. Study the impact on QMS of possible actions in the Patent Department
9. Monitoring of the results of quality control on products

Also Quality Committee meets every six month in order to do a follow up of the actions approved in the annual review meeting.

To assure the reports issued are compliant with the PCT Guidelines various controls are set up during the process of search and examination. One of those is monthly done on issued reports by the head of technical units and its results are feedback at the moment to the examiner, when necessary, and every three months in the meetings of QMG.

To determine the extent to which the QMS is based on Chapter 21, before the QMS was first implemented at SPTO an study was done about the correspondence between Chapter 21 and ISO 9001:2000. At that time the Authority concluded that fulfilling all the requirements of the ISO standard assured the complete fulfilment of Chapter 21.

Now a days, with the change of chapter 21 this could also be assured, but since it has new and more specific requirements related to Industrial Property itself, the office has decided to include it, from now on, as one point of the internal review meeting.

## 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.**

SPTO continuously holds a management control for every operative unit which assures control over fluctuations in demand and possible job accumulation. This allows SPTO to adapt its financial and human resources accordingly.

Maintenance of the technical qualifications to search and examination in the required technical fields; and also of the qualifications of the Administrative staff is assured by our recruiting program and also by yearly training plan.

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.*

(a) The SPTO IT department is in charge of maintaining and monitoring the IT software and hardware. According to the specific procedure established for Maintenance of the equipment, this department plans and records all reviews done in order to fulfil the requirements established on ISO 9001:2008.

New applications are identified and updated in a permanent way. There is a continuous communication between PCT responsible people and IT dpt. to maintain updated all PCT support software.

The SPTO has guaranteed that our examiners can have access to the PCT minimum documentation as defined in Rule 34 PCT.

EPOQUE database and specially the Viewer and BNS have been an important source of documents.

Access to Spanish documentation, not completely present at EPO databases, is assured by using database INVENES which includes all the digitised Spanish documentation.

Regarding the documentation written in Spanish from 18 Latin-American countries, hard efforts have been done in order to assure the exchange of documentation between these countries. As a result of this cooperation, the SPTO has created the database LATIPAT in co-operation with National Offices of Latin-America, WIPO and the EPO.

Through EPOQUE, the SPTO has access to WPI and also to a number of NPL databases. At the same time, we maintain a contract with STN for external access and through Internet all SPTO examiners can access to NPL databases such as ip.com.

New databases are identified and evaluated by the Head of the Documentation Area, who participates in all the relevant meetings and Fora in collaboration with the Heads of Technical Areas.

(b) PCT Search and Examination Guidelines are electronically accessible. Also, in order to contribute to the harmonization between examiners, a full set of electronic standard clauses have been developed.

All the examiners have been provided with detailed information on PCT procedures through the set of different procedures included in the quality management system documentation, the update version of this documents is available to all the examiners at Inc@web application.

All the documentation relevant for QMS is controlled according to the Documentation Control procedure established in the SPTO by the requirements of ISO 9001:2008.

*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.*

A harmonised and continuous Training Program is established for all the staff, ie:

- Patent Law Seminars (PCT Procedure Revision, PCT new Guidelines, etc)
- Technical and Analytical Skills (Technical courses on specific fields, work visits, Exchange Programme Examiners)
- PC Skills and operation of electronic tools (Epoquenet, specific Databases, etc)
- Classification Systems Seminars (IPC, ECLA, F-terms)
- Search and Examination Skills (seminars on Novelty, Inventive step, Complex Applications, Non Unity, etc)
- Language Training Courses

Every year, the training program is evaluated and updated accordingly to this evaluation.

*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*

SPTO continuously holds a management control over every operative unit which assures control over fluctuations in demand and possible job accumulation. This allows SPTO to adapt its financial and human resources accordingly.

### **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.*

SPTO examiners can control the time limits of their files through Data warehouse informs; this tool helps them on the timely issue of the reports. Also the Heads of Technical Units have informs that help them control the backlog and the timely issue of the reports assigned to the examiners.

The SPTO is, at present, developing an electronic workflow tool which includes an alert system to control timely issue of the reports; this tool will be completely introduced by the end of 2010.

### **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.*

SPTO reviews a representative sample of search reports issued by the office each month.

This review is registered through a checklist which helps assure that search reports and written opinions meet the expected levels of clarity, consistency and reliability. It also includes formal aspects.

The sample is chosen taking into account the number of applications in each Technical Unit. The result is recorded in Inc@web application and is analyzed in the Quality Management Group of the Patent Department, where improvement actions will be approved when necessary. Is a key tool of the QMS as a source of information for improvement actions.

From October 2010 on this system will be applied to all of the International Preliminary Report on Patentability.

Process indicators are set and reviewed at the quality group meetings in order to verify the conformity of the process and to approve improvement actions of the processes when necessary.

Also non conformities, corrective and preventative actions are studied at the Quality Management Group of the Patent Department, their implementation is followed up and also their effectiveness is verified at the QMG meetings.

## 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.*

The Quality Advisor of the SPTO, Gerardo Penas and the Quality Assessor of the Patent Department, Isabel Serriñá are the designated contact persons for this Authority.

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.*

All the **complaints** received by the office are handled according to the Complaints Management Procedure included in the certified QMS. All the information is registered in a specific application that is used for complaints management.

This information is analyzed by the Quality Management Group of each department in order to decide corrective actions if necessary.

The evaluation of the customer satisfaction has been carried out through two **customer satisfaction surveys** implemented by questionnaire. One related to applicants and another one related to patent attorneys.

SPTO hires an external organization to carry out the survey and analyse the data from the questionnaires. They got in contact with applicants and attorneys by email and provided them with a link, user and password so that they could access the website where the survey was being implemented and write their answers to the questionnaires on line.

The information obtained from the **surveys**:

- Level of Satisfaction of applicants and attorneys with the main aspects of the service provided by the SPTO regarding the PCT Process.
- Level of Importance that Applicants and Agents consider for each of those aspects.
- Qualitative information about the service provided in the form of comments, suggestions or expectations extracted from open response questions.
- Strengths and areas for improvement, as a result of data analysis.



is analyzed by the Quality Management Group who proposes actions based on this analysis to the Quality Committee who is responsible for the approval of these actions and the necessary resources.

The frequency of the evaluation is once a year. For the last three years only those areas within the scope of the certified system were included in the survey. In 2010, all the products will be included.

The SPTO assures concise and comprehensive **guidance and information to users** (particularly unrepresented applicants) on the S&E process using the SPTO website.

An specific site is established in the SPTO web dealing with PCT and the activities of the Office as International Authority. A complete and clear information and help is given to the applicant in this site (general PCT information, applicant forms, fees, patent databases, PCT brochures and online filing). Together with the commitments included in our **Quality Service Charter**, the SPTO includes periodically in its web page the relevant information for applicants.

Also, regular sessions of the Innovation and Patents Forum, formed by the main actors of the patent system in Spain, are held periodically since 2002. Those sessions include an specific part dedicated to Quality, specifically in the framework of the PCT.

*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*

According to these guidelines, the Spanish Patent & Trademark Office, as an International Searching and Preliminary Examining Authority, has implemented a communication channel with the Receiving, Designated and Elected Offices through a specific restricted access within our website. This new channel, to receive comments, suggestions and complaints with respect to PCT files under their responsibility, is included in the Quality Microsite of SPTO.

## 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.*

21.22 *Indicate whether the documents making up the Quality Manual include the following:*

- (a) the quality policy of the Authority including a clear statement of commitment to the QMS from top management;*
- (b) the scope of the QMS, including details of and justification for any exclusions;*
- (c) the organizational structure of the Authority and the responsibilities of each of its departments;*
- (d) 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;*
- (e) the resources available for carrying out the processes and implementing the procedures; and*
- (f) a description of the interaction between the processes and the procedures of the QMS.*

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.*

Management of the QMS documents and records is done according to the established procedures, which are included in the system and are compliant with ISO 9001:2008 standard.

The SPTO has developed a documentation management system called Inc@web, accessible to all the staff involved in QMS.

Inc@web contains the updated Quality System manual and procedures, and associated documentation.

Also, most part of QMS records are registered on this system. The management of the records which are not included in Inc@web is done according to the Record Management Procedure. This procedure is compliant with ISO 9001:2008 requirements.

There is a Quality Manual at the SPTO where all procedures and processes and their interactions included in the scope of the QMS are documented. Also, the scope of the system is included in this Manual.

As we have described in the above sections, Guidelines and working instructions for all the staff are electronically accessible.

## 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.*

The SPTO has until November 2010 a tool called Examiner Desk, with a section where search strategies are recorded, this record included:

- Databases consulted (patent and non patent)
- Keywords and combination
- Language in which the search was carried out
- Classes and class combination searched
- List of search statements used

From November 2010 on we will have a new workflow tool called Alfa, that has integrated recording of search strategies with the same elements as before.

The search strategy record will reflect any of the special cases included in point c), and documents of reference when necessary.

## **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*

No further inputs than those that appear on points 21.04-21.09

## **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]