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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 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 includes: PCT procedure, Technological Watch procedures, Industrial Design, National trademarks and commercial names, National Patents, Utility models, Inscription of licensing and transfer agreements over industrial property rights, Decisions on restoration and rehabilitation of rights, Appeals and Validation of European Patents.

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 organizational 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.

A review of this Quality policy was approved in September 2013. It contains the same basic principles as before, but includes the compromise of the office with the promotion of electronic tools as a way to ease the filling of applications to users and also as a way of speeding up the management of applications afterwards.

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 selfevaluation 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.

The QMS responsibilities at the SPTO are organized in two levels: an independent body b) 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.

The bodies and individuals responsible for the QMS are described at the Quality Manual. C)

The updated version of the Quality Manual is available at the SPTO intranet 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.).

part no

~

√

Chapter 2	21 requi	rement		ent of plianc	e
			full	part	n
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	✓		T
	(b)	Quality objectives are reviewed	✓		

Communication of quality objectives throughout the Authority

Performance of a yearly internal review of the QMS in/to

[Sample table, to be amended as necessary]

(c)

(a)

21.09

Chapte	hapter 21 requirement		Extent of compliance			
				full	part	no
		(b)	determine the extent to which the QMS in based on 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 21.1224	✓		
		(e)	recording the results	✓		
21.10			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 tech. 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 records	✓		
	(iii)		Ensuring appropriate equipment to carry out S&E	✓		
	(iv)		Ensuring documentation accord. to Rule 34	✓		
	(v)	(a)	Instructions to help staff understand and act accord. 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	~		
21.11	(i)	1	Control mechanisms to ensure timely issue of S&E reports	✓		1
	(ii)		Control mech. regarding fluctuations in demand and backlog	✓		
21.12	(i)		Internal quality assurance system for self assessment			
		(a)	for compliance with S&E Guidelines	✓		

Chapter 21 requirement			Extent of compliance			
				full	part	no
		(b)	for channeling feedback to staff	✓		
	(ii)		System for measurement of data and reporting for continuous improvement	~		
	(iii)		System for verifying the effectiveness of actions taken to correct deficient S&E work	~		
21.14		(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	~		
21.15	(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	✓		
	(iv)		Indication where and how the Authority makes its quality objectives publicly available	~		
21.16			Established communication with WIPO and designated and elected Offices	~		
21.17			QMS of Authority clearly described (e.g. Quality Manual)	✓		
21.18		(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	✓		
21.19	(i)	1	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.	~		
21.20	(i)	1	Records which documents are kept and where they are kept	✓		
	(ii)	1	Records of results of management review	✓		

Chapte	er 21 req	quirement		Extent of compliance		
			full	part	no	
	(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	✓			
21.21	(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	✓		1	
21.22		Report on its own internal review processes	✓		1	
21.23- 21.25		Additional information on further inputs to its internal reviews	~			
21.26		Initial report called for by paragraph 21.26	✓	1	1	

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 <u>and Sections</u>, both administrative and technical, the Director of the Patent Department, the Quality <u>Assessor Manager</u> of the Patent Department<u>and the Quality Advisor of the SPTO</u>.

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 analyse 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 non conformity 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 21.22-21.25:

- (a) at least once per year (cf. paragraph 21.22);
- (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 21.22, 21.24(i));

to determine the extent to which Search and Examination work complies with PCT Guidelines (cf. paragraphs 21.22, 21.24(i));

- (c) in an objective and transparent way (cf. paragraph 21.22);
- (d) using input including information according to paragraphs 21.24 (ii)-(vi);
- (e) recording the results (cf. paragraph 21.25).

Management review is held every twelve months by the <u>Quality Committee</u> (QC). Also there is follow-up meeting every six months.

Previous to this review, the <u>Quality Management Group</u> (QMG) 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 the 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 QC, decides which improving actions and budget for Resources and Infrastructure are necessary

The minutes of these two meetings are <u>published and</u> accessible to all the staff of the Department through our documentation management tool, Inc@web our <u>SPTO intranet</u>. <u>These</u> <u>meeting Minutes include all the information about quality objectives and their follow up, as well</u> <u>as indicators.</u> <u>Also quality objectives and their follow ups, as well as, indicators are also record</u> on this application, this <u>.</u> <u>This</u> way we assure that <u>all the</u> staff involved in QMS have access to this information.

Every three four 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 QC meets every six month in order to do a follow up of the actions approved in the annual review meeting.

To assure that the reports issued are compliant with the PCT Guidelines several controls are set up during the process of search and examination. One of those <u>controls</u> is monthly done on <u>a</u> <u>sample of</u> issued reports by the head of technical <u>units</u> <u>sections</u> and its results are feedback<u>ed</u> at the moment to the examiner, when necessary, and <u>commented on QMG meetings</u>. <u>every</u> three months in the meetings of QMGAlso this information is deeply analized in the Internal Review meeting to identify improvement actions.

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.

Nowadays, 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 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.

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 by our yearly training plan. As an example, in 2015 there has been specific courses on wind turbines and nanotechnology.

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.

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.

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

Access to Spanish documentation, not completely present at EPO databases, is assured by using our database called INVENES, which includes all the digitised Spanish documentation. Regarding the documentation written in Spanish from 18 Latin-American countries, SPTO has created the database LATIPAT in co-operation with National Offices of Latin-America, WIPO and the EPO.

New databases are identified and evaluated by the Head of the Documentation Area in collaboration with the Heads of Technical Areas.

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 documentation of the quality management system. The updated version of these documents is available to all the examiners at <u>SPTO intranet</u> Inc@web application.

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

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.

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, CPC, 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.

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.

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

21.11 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:

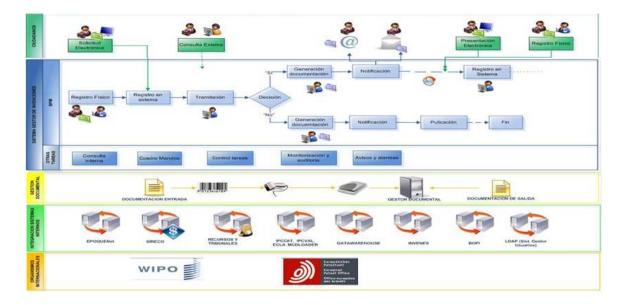
(i) Effective control mechanisms regarding timely issue of search and examination reports to a quality standard as set by the respective Authority; and

(ii) Appropriate control mechanisms regarding fluctuations in demand and backlog management.

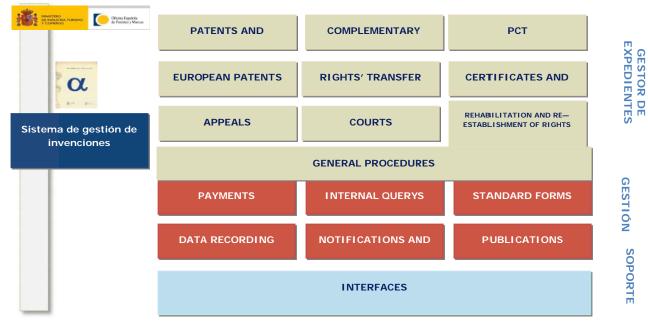
ALFA is the electronic workflow tool implemented by SPTO since November 2010:

• It is a Business Process Manager. It works with Patent applications according to a defined Process model.

- It is a tool that allows the end users to interact with applications management
- It is integrated with external systems and organisms
- Alfa registers and keeps a record of all application data and how such applications are being processed
- Includes an alert system to control timely issue of the reports



ALFA includes many functional subsystems:



The system has interfaces with:

- Content Management System
- eOLF

- Official Gazette (BOPI)
- IPCCAT
- LDAP
- SPEP (Publication Service)
- Payment System

Also, Heads of Technical Units have Dataware reports that help them control the backlog and the timely issue of the reports assigned to the examiners.

4. QUALITY ASSURANCE

21.12 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, including the use of any checklists to verify reports before their issue or for monitoring the quality standard 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.

SPTO reviews a representative sample of Search Reports and 100% of International preliminary examinations 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 of Search Reports is chosen taking into account the number of applications in each Technical Unit. The <u>verification through the checklist is registered in an specific application called: "Application for Quality Management".Inc@web application and isThe results are analyzed in the Quality Management Group of the Patent Department, where improvement actions will be approved when necessary. It is a key tool of the QMS as a source of information for improvement actions, for example, to identify needs of training. These results are also feedbacked at the moment to the examiner, when necessary.</u>

ALFA has also had an impact in the quality assurance systems, especially in quality control, since the tool includes a record of the quality review done by Heads of Technical Units Sections prior to the issue of all the Reports.

This sort of review was already done in the past, but thanks to the tool, we can record comments done during this evaluation and extract this information afterwards.

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

Inter-Authority communication:

21.13 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 21.13)

21.14 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 Representative of the SPTO, Antonio Cano and the Quality Assessor of the Patent Department, Isabel Seriñá are the designated contact persons for this Authority.

Communication and guidance to users:

21.15 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.

(iv) 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.

Annually at SPTO, we carry out several studies to get feedback from users and information about their satisfaction. We have used in the past different ways to evaluate user satisfaction, from surveys, some of them together with the Spanish Association of Patent Attorneys, to Focus Groups, sessions with users in which, with the help of an independent moderator, they express their opinions and suggestions about the different aspects of the service provided by the SPTO. All these studies are carried out in the framework of our ISO 9001:2008 certified Quality Management System (QMS), and therefore their scope is normally the IP rights which are

included in our QMS.

Regarding the timing, they are usually done before our annual Audit June/July so that we can use the results in the Internal Review of the QMS.

The results of these studies are used as inputs to the Quality Management Group in each department, where improvement actions are taken.

In 2012 we used Focus Groups for PCT. In 2013, we launched several user satisfaction surveys using the deliveries of the CF1.2.7 OHIM Cooperation Fund Programme, Harmonised User Satisfaction Survey on Trademarks and designs, in which SPTO took part in the working group. Among then, we launched a Survey on PCT and National Patent.

In 2014, and regarding the planning of surveys, it was decided that, in order not to disturb users (especially patent attorneys) with too many requests to participate in these studies, surveys would be launched every two or three years. As a general rule, a survey launched the previous year will not be launched the current year. This way, implementations and changes in the service will be perceived better by the user from one survey to the next one.

In 201<u>5</u>4 the following User Satisfaction Surveys (USS) has been launched (all of then OEPM insourced surveys):

- USS on Appeals
- USS on Technology Watch Bulletins
- USS on the Information service provided by the Patent Examiner on duty.
- USS on the SME Support Service
- USS on Patent Technological Reports
- USS on Retrospective searches
- USS on Customized Technological Monitoring Reports
- USS on ALFA (internal survey)
- USS on Validation of European Patents
- USS on "Examiner on call" service
- USS on the SME Support Service
- USS on Patent Technological Reports
- USS on Retrospective searches
- USS on Customized Technological Monitoring Reports

The SPTO assures concise and comprehensive **guidance and information to users** (particularly unrepresented applicants) on the S&E process using the SPTO website. Through that page users can also find the Micro site on Quality. This location includes information on:

- Quality Policy of SPTO
- Service Charters
- Scope of the QMS system
- Results of User Satisfaction Surveys
- Channels to get in contact with SPTO, including how to file suggestions, comments and complaints

A 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.

In October 2014, our PCT Quality Service charter as International Search and examination Authority has been updated with a new design.

Follow up data of our service charters are monthly published in our Quality website.

Also since 2013 a special service for face to face information has been established. It is called "On call Examiner". This service is given by patent examiners, in assigned turns. They give direct assistance to applicants, which come to our office searching for information regarding technical issues. They provide this service also by telephone and by e-mail.

And since 2002, regular sessions of the Innovation and Patents Forum, formed by the main actors of the patent system in Spain, are held.

21.16 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.

Communication with WIPO and designated and elected offices is done through the PCT Service of the SPTO. This service belongs to the Patent Department of the office. PCT Service addresses all feedback given by WIPO or designated and elected offices to the Department management.

Communication with the International Bureau of WIPO is mainly provided via PCT-EDI, by email, facsimile and telephone.

6. DOCUMENTATION

21.17 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 21.18).

(Note: This point is informative. No response is required by the template to paragraph 21.17)

21.18 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.

21.19 Indicate whether the documents making up the Quality Manual 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.

21.20 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.

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.

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.

The Quality Manual together with procedures and relevant documentation of the QMS are available to all our staff through the SPTO intranet. This documentation is created and updated according to the Documentation Management Procedure. This procedure is compliant with ISO 9001:2008 requirements.

Also, most part of QMS records are registered <u>and managed on an application called:</u> <u>"Application for Quality Management".</u> on this system. The management of the records which are not included in <u>this application</u> 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

- 21.21 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.

ALFA, includes a screen for recording search process documentation.

The record includes:

- 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. This application can import data from Epoque in order to compile the search statements used by the examiner during the search.
- Possible comments regarding the search done by the examiners.

As said before, some of this search process documentation is automatically retrieved from Epoque and some other can be completed by the examiners.

8. INTERNAL REVIEW

21.22 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.

21.23-21.25 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

21.26 There are two stages in the reporting arrangements outlined in Chapter 21: the initial report called for by paragraph 21.26(a), and supplementary annual reports in accordance with paragraph 21.26(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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