PATENT COOPERATION TREATY

Common Quality Framework for International Search and Preliminary Examination

Report Under Paragraph 21.17 of the PCT International Search and Preliminary Examination Guidelines

by:	SPANISH PATENT AND TRADEMARK OFFICE		
	(SPTO)		

on: Dec. 2006

Documents referred to in this report:

[list any documents which appended to the report for information or publicly available documents which are referred to]

INTRODUCTION (PARAGRAPHS 21.01–21.02)

The Authority should provide general background information relevant to the quality management system (QMS). The following may be included, if applicable:

• Recognised normative reference or basis for quality management system besides Chapter 21, e.g. ISO 9000.

• An organigram showing at least the organisational units responsible for implementation of the Authority's QMS. It could be referred to in the rest of the report, as necessary.

SPTO Quality policy is defined within the parameters established by ISO 9001:2000 standard. Thus, SPTO has defined a quality policy to assure the user's best performance of the International PCT Service, by adopting a Quality Management System that contributes to the continuous improvement of its processes. For it, the General Direction is committed to provide with means, human as material, as much necessary for the development and unfolds of this Policy within the whole Organization.

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 required by the affected 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 to 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. Implying to 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.

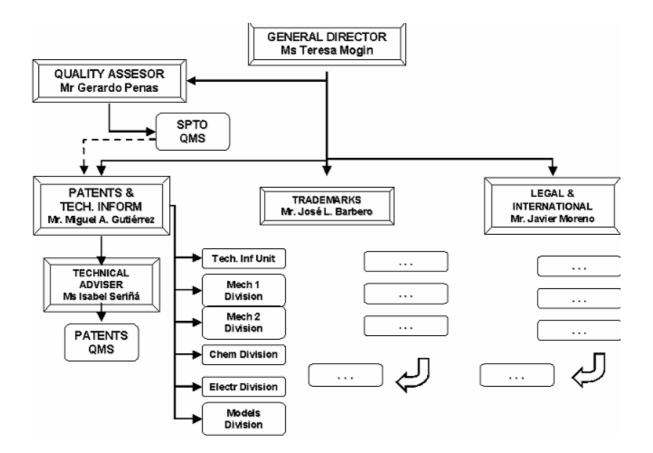
7. Establishing the continuous improvement as a priority of the management, by measuring, analyzing and interpreting the results of the processes and maintaining permanent communication with users, personnel and suppliers as sources to detect possible improvements in the quality of given services.

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

In order to achieve these objectives, the Management contributes with the human and technical resources necessary to assure the quality in the benefit of the service, including the continuous adaptation of the personnel to the functions that they perform through a continuous training.

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

The organigram regarding QMS can be represented as follows:



In the SPTO, there is an independent body responsible for quality managed by a Quality Advisor (Mr Gerardo Penas). He depends directly on the Director General . In the Patent Department Quality management is structured in two levels: a Quality Management Group and a Quality Supervisory Group.

QUALITY MANAGEMENT SYSTEM (PARAGRAPHS 21.03–21.09)

Establishment and maintenance of QMS (Paragraph 21.03)

The Authority should show that it has established and is maintaining, or is establishing, a QMS which:

(a) sets out basic requirements regarding resources, administrative procedures, feedback and communication channels required to underpin search and examination (S&E);

(b) incorporates a quality assurance scheme for monitoring compliance with these basic requirements and with PCT/GL/ISPE.

Quality Management System

Quality Management System in the SPTO in the frame of the PCT and its activities as International Searching and Examining Authority, is based in the overall harmonization in Search and Examination tasks as well as in the harmonization of support staff work.

This harmonization is achieved by:

 Setting up Instructions concerning the application of the Patent Cooperation Treaty and PCT/GL/ISPE.

- Training Plan
- Exchange of views within Examining Divisions and between the support staff
- A quality assurance system to supervise the PCT procedure and final product (Search and Examination reports done by examiners).

In 2006, the SPTO has launched the project to certify the PCT activity under ISO 9001:2000. At this moment, we are in the process of documenting all the procedures regarding PCT, and checking if the office complies with all the requirements of ISO 9001:2000.

Structure of the Quality Management System

The SPTO has put into operation a *Quality Management Group* which plays a central role in the Quality Management System. The Quality Management Group is formed by 7 members related with all the activities within the PCT procedure, both administrative and technical. The group has been authorized to:

- 1. Conduct initiatives to obtain indicators about the Quality Status.
- 2. Prepare reports which will be presented to the Supervisory Board.
- 3. Analyze nonconformity reports.
- 3. Prepare preventive or corrective actions carried out in the operative units.

The Quality Management Group reports to the Quality Supervisory Board, chaired by the Director of the Patent Department and formed by all the Heads of the Operative Units.

The Quality Supervisory Group has as main functions:

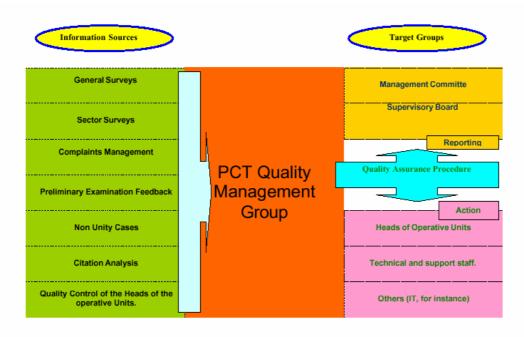
- 1. To approve or disapprove the reports or actions of the Quality Management Group.
- 2. To solve the disagreement between the Heads of the Operative Units and the Quality Management Group.
- 3. To prepare the report that the chairman of the group will present to the Committee of Direction.

The *Committee of Direction* is chaired by the Director General of the SPTO. The members of the Committee of Direction are the Directors of the different departments of the SPTO: General Secretary, Patents, Trademarks and International Relationship Department and a person responsible for quality. The main functions of the Committee are:

- 1. To approve the executive Report prepared by the Supervisory Group and reported by the Director of the Patent 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.

The actions of the Quality Management Group are addressed to the Operative Units. These Operative Units are divided into Technical Units and Administrative Units, depending on the type of work they usually perform. The role of these Operative Units is:

- 1. To implement the actions proposed by the Quality Management Group.
- 2. To prepare regular reports for the Quality Management Group on Quality issues that have been detected.



Structure of the QMS at the SPTO

Resources - infrastructure (Paragraph 21.05)

Provide information about the infrastructure in place which ensures the following:

- (a) Adequate quantity of search and examination (S&E) staff, including:
 - (i) means for matching the quantity of S&E staff to the inflow of work;

(ii) means for ensuring that recruited S&E staff have the necessary technical qualifications;

(iii) means for ensuring that S&E staff have language skills, or have access to supporting translation arrangements, as necessary to meet Rule 34.

- (b) Adequate quantity and skills of administrative staff to support S&E.
- (c) Provision of appropriate equipment and facilities to support S&E.
- (d) Provision of the minimum documentation supporting S&E, as referred to in Rule 34.
- (e) Provision of up-to-date work manuals. These must include explanations of:
 - (i) quality criteria and standards;
 - (ii) descriptions of work procedures;
 - (iii) instructions ensuring that the work procedures are adhered to.

(f) Provision of an effective training and development program for all staff involved in S&E, including means to ensure the acquisition and maintenance of the necessary experience, skills and familiarity with work manuals.

(g) Continuously monitoring and identifying resources, other than staff, required to deal with demand and comply with quality standards for S&E.

(a) Technical staff working at the SPTO comprises 142 Examiners having the technical qualifications (MS Engineering, Architecture or Science -Physics, Chemistry,...-degree) to search and examine in the required technical fields and mastery of languages to level needed to be able to read and understand technical texts, especially patent documents.

Examiners are organized into 4 Technical Divisions (2 mechanics, one physics and electricity, and one chemistry)

Once a year a elaborated Business Plan is issued to forecast the futures necessities on manpower and other resources. As a result of it, provisions are made to cope with the previsions for the coming year.

The competencies required for the examiners are the following:

- Technical & analytical skills
 - University level degree in a technical subject is a pre-requisite for examiners.
 - o Classification skills
 - PC skills & operation of electronic tools
 - Search strategy & search execution skills
 - o Drafting skills
- Patent law skills
- Linguistic skills

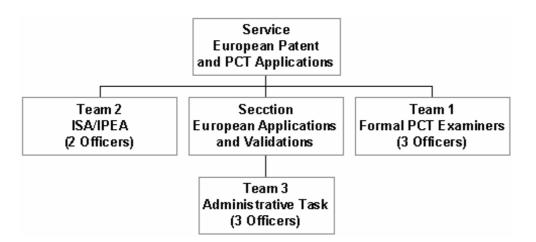
Recruitment of Examiners is an open competition consisting of different and selective exams that include:

- Items regarding to:
 - Spanish Public administration
 - National, European and International Laws and Regulations on Industrial Property (Patentability, Novelty, Inventive Step, Granting procedures, etc)
 - o Technological Information and Documentation
 - o Classification of patent documents
 - Elaboration of an abstract of a patent application
 - o Search Report
 - Languages: English and other (French or German)

(b) Administrative Staff

The PCT administrative activities is performed by the Service of European Patent and PCT Applications. This Service hierarchically depends on the Administrative Legal Division of the Patent and Technological Information Department.

All the staff assigned to this Unit has the condition of civil servants of the Spanish Administration. Its composition is as follows: A Head of the Administrative Unit pertaining to the Corps of Management of the General Administration of the State; 1 Administrative, Group leader; 3 Administrative; 2 Administrative assistants. The administrative and the Administrative assistants belong to the Corps Administrative and Auxiliary of the General Administration of the State.



The recruitment and selection of administrative staff has two levels:

• Selection within the framework of the Spanish General Administration.

The SPTO is an Autonomous Institution assigned to the Ministry of Industry, Tourism and Commerce. Therefore, access to the public function is determined by the national laws, which regulate the procedures of access. Consequently, all the civil employees of the SPTO have acceded to the Administration through those procedures. The selection trial is made through different exercises to determine the knowledge degree of the candidate.

• Selection within the framework of the SPTO.

The candidates that comply with general conditions and particular requirements may apply for the post. Particular requirements are described in the next table:

Description of the Job	Courses required	Specific Merits
 Formal examination	 * Related to Industrial	 * Experience in
and procedure of	Property, National	administrative procedures. * Knowledge of
PCT international	administrative	administrative procedures,
applications. Control, registry and	procedure and PCT. * Office computerization.	special in Industrial
verification of PCT	Knowledge of data	Property and PCT. * English and/or French
applications	bases	Knowledge

(c) Provision of appropriate equipment and facilities to support S&E

The equipment used by the personnel of the patent department has the following characteristics:

Patent Examiner's equipment

The Standard Hardware and Software used by the examiners has the following features:

• Standard Hardware for SPTO Examiners:

Pentium IV RAM memory above 750 Mb 20 inches TFT flat screen Laser individual Printer

 Standard Software for SPTO Examiners: WINDOWS XP EPOQUE Escritorio del Examinador (Examiner's Desk) e-Phoenix/MADRAS STN Express EBI Mistral Query (OEPMPAT) MENURPI/SITADIN (legal status) TPAD Access (STN, INPADOC) Microsoft Office 2000 Internet

SPTO examiners are using high standard Databases in search and examination activities. There are both national databases (OEPMPAT) as well as external ones (EPODOC, WPI, PAJ, CAplus, others).

Connections to EPODOC, WPI and PAJ are made through EPOQUE to recover complete documents (BNS or Viewer).

All examiners have a permanent online access to the databases through their own workstation. Those databases are accessible to the examiners by intranet and fast specific on-line connections through PATNET 2 and a dedicated 2 MBps line.

Non Patent Literature documents are also accessible on line through different databases, such as BIOSIS, MEDLINE, COMPENDEX, IEEE, etc.

The Examiner's Desk (Escritorio del Examinador): an electronic tool for examiner's communications

Software entirely developed by the SPTO aimed to assist the examiner in the realisation of the technical work. This software has been developed in a Visual Basic environment, with a comfortable structure and presentation. The examiner must only contribute to the real added value (novelty, inventive step, unity, clarity,..)

The software makes the automated capture from the Office Datawarehouse: applicant, agent, address, number and date of priority, date of presentation, etc., which are integrated in the notification avoiding possible errors and making the accomplishment of the notification very agile.

The inclusion of standard clauses according PCT regulations helps the examiner for the completion of the form and it supposes both quality and technical rigor in the emitted notification.

The Examiner's Desk also includes the necessary technical manuals.

All RO, ISA and IPEA electronically editable forms have been integrated in the Examiner's Desk. This facility allows the procedure to be electronically handled.

EDI Project

SPTO has developed an electronic system for sending PCT forms internally and is also sending them through Electronic Data Interchange (EDI) to WIPO.

SPTO has also deployed a new software to recover full facsimile patent documents from the Internet in a freeware environment improving the possibilities to recover patent documentation.

The SPTO uses the Global Index database, an EPO software that allows on line access to the full collection of CD-ROMS. This tool provides a backup document delivery service for the examiners and the users. So far, the complete collections of EP

and WO have been loaded.

Another important tool for examiners is the Virtual Documentary Database. It allows going into the Spanish patents and utility model in facsimile electronic format. It has the advantage of the speed in which the documents are downloaded. The complete documents can be consulted or printed. The access is made through the Examiner's Desk by means of the introduction of the international classification. Its use is recommendable when it is required to consult a complete classification quickly. It is equivalent to the old card boxes with documents in paper.

- Administrative Unit personnel equipment
 - Standard for Hardware SPTO Administrative Unit. Pentium III Ram memory 129Mb 20 inches TFT flat Screen individual Laser Printer
 - o Standard for Software SPTO Administrative Unit.

For the development of the administrative tasks in the frame of the PCT activities, the unit has a database for consultation of the applications, SITADIN and the tool" Examiner desk" for the generation of RO, ISA and IPEA forms. This tool directly captures the data of identification of the SITADIN requests.

The following Software for use of the Unit is detailed: WINDOWS XP

The Examiner's Desk e-Phoenix/MADRAS MENURPI/SITADIN Microsoft Office 2000 eOLF and PCT-SAFE Internet

(d) Provision of the minimum documentation supporting S&E as referred to in Rule 34.

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

From the 80ths there has been a continuous effort to improve the documentation in the SPTO using different traditional formats: paper, microfiche and microfilm. As a result of this effort, the inventory of documents at the Spanish patent Office library sums up more than 20 millions.

As the technology has evolved very quickly, we started to incorporate documents in other formats, specially in CD-R and, more recently, in DVD. At this moment, the library has more than 7.000 CDs.

Online databases have also played an important role to make access to this documentation easier and quicker. EPOQUE database and specially the Viewer and BNS have been an important source of documents. According to the statistics provided by the EPO, the SPTO is one of the main users of the service among the National Offices.

Access to Spanish documentation, not completely present at EPO databases, is assured by using database MISTRAL which includes all the digitised Spanish documentation. This documentation is also accessible in paper.

Speaking about 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 results of this cooperation, the SPTO has created the database LATIPAT in co-operation with National Offices of Latin-America, WIPO and the EPO. More than 500.000 bibliographic data and 125.000 images are available on the website lp.espacenet.com.

Through EPOQUE, the SPTO has access to a number of NPL databases: Compendex, Biosis, Elsevier, and WPI. At the same time, we maintain contracts with STN for external access and through Internet all SPTO examiners can access to NPL databases as Thompson Web of Knowledge and ip.com, defensive publications. Concerning the NPL documents, the SPTO maintains a Consortium Agreement with the Official Research Council in Spain. This Research Council has one of the most comprehensive network of libraries specialised in almost every field of technology. Under this agreement, the Council provides the SPTO with a copy of the NPL articles upon demand. In specific cases, the British Library also provides this type of information.

Increasingly important is the access to the publisher databases. At this respect the examiners can access to the full text databases of the following publishers:

- -American Institute of Physics.
- -American Physical Society.
- -Blackwell
- -Cell Press
- -ACM Libraries.
- -Kluwer
- -Springer
- -Nature
- -Elsevier
- -Wiley.

SPTO has made a great effort in order to increase the number of digitized Spanish language patent documentation going to the oldest documents in our archive. Also these records have been sent to the EPO to be integrated in the EPOQUE system to be shared.

The SPTO is participating actively in the European Machine Translation Project, led by the EPO and focusing to put the Spanish documents at the disposal of all the English speaking countries. An automatic translator english-spanish has been recently implemented in <u>esp@cenet</u>. This system fully translates any patent document written in English (50 Millions) into Spanish. This was the result of the cooperation between the EPO and the SPTO.

An updated version of the SYSTRAN automatic translator has been put at examiner's disposal.

The SPTO has also benefited from a National License of the well –known and leader scientific product "Web of Knowledge".

Finally, the SPTO is committed with the maintenance of the translation of the IPC 8th edition into Spanish.

At the same time, the SPTO is providing the EPO with the European Classification of the Spanish published documents.

(e) Provision of up-to-date work manuals.

(i) quality criteria and standards;

PCT Search and Examination Guidelines have been included electronically in the "Examiner's Desk" with the possibility of searching and consulting specific matters in a faster way than the regular PDF format. Examiners are addressed on Ch. 21 to comply with quality standards. As an example, in order to contribute to the harmonization between examiners, a full set of electronic standard clauses have been included in the Examiner's Desk.

Finally, SPTO is now in the process to be certified under ISO 9001:2000. In this process we are developing an even more complete set of quality documentation;

(ii) descriptions of work procedures;

All the examiners have been provided with detailed information on PCT procedures through the set of different Guidelines and manuals.

(iii) instructions ensuring that the work procedures are adhered to.

A set of specific PCT internal instructions such as: Handling of new documents arriving during the PCT procedure (i.e. Art 34 modifications), PCT Deadline Accomplishment, Full Reports revision by Unit Heads, etc have been issued and included in the Examiner's Desk.

New instructions are continuously transmitted to all PCT staff, such as modifications entering into force in April 2005.

(f) Training Program

A harmonised and continuous Training Program is established for all the staff involved in Search and Examination, 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.

(g) Continuously monitoring and identifying resources, other than staff, required to deal with demand and comply with quality standards for S&E.

IT department is in charge of maintaining and monitoring the IT software and hardware. 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.

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

SPTO is also working in the identification of new necessities and developing on our own or in collaboration with other Offices new tools and resources (such us new IPC Spanish Portal in WIPO, LATIPAT database. Electronic Data Interchange (EDI) to WIPO, etc)

Administration - procedures (Paragraphs 21.06(a) and (b))

Provide information on those administrative procedures and control mechanisms which ensure the following:

(a) Timeliness of S&E and related functions, to quality standards in accordance with PCT/GL/ISPE.

(b) Coping with fluctuations in demand and backlog management.

(a) Timeliness of S&E and related functions, to quality standards in accordance with PCT/GL/ISPE.

Related to control mechanisms regarding timely issue, the SPTO Data Warehouse system provides two specific elements to comply with all timely requirements: An electronic routing sheet for every dossier and one data and time limit sticker. In addition to the legacy data provided by the system, the technical information related to preclassification is also included. These elements are being very useful and very effective to maintain the procedure under the strictest requirements related to terms. This tool gives also the possibility of developing different kind of reports depending on the data needed (I.e. reports to control the issuing of international preliminary examination reports, reports to control the issuing of international search reports,...)

The PCT Service Charter is in force since January 2005. This service charter includes commitments on timeliness for every single PCT application. According to the rules, the results of the PCT Service Charter will be transparent and public and will be found in the web page <u>www.oepm.es</u>. A revision of the PCT Service Charter is underway and it probably will extend to all the operations of the SPTO as a PCT Authority.

(b) Coping with fluctuations in demand and backlog management

SPTO continues to hold 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.

The SPTO Business Plan forecasts estimated deviations on PCT workload, and hence providing human and economic resources for different scenarios.

Quality Assurance Procedures (Paragraph 21.07)

Provide information on procedures which ensure that S&E reports of a quality standard in accordance with PCT/GL/ISPE are issued. In particular, provide information on:

(a) Activities related to verification, validation and monitoring; as carried out in order to assess compliance of S&E work with PCT/GL/ISPE.

(b) Processes for measuring, recording, monitoring and analysing performance of the QMS to assess its conformity with the requirements of Chapter 21 and, if applicable, any other normative reference for the QMS.

(c) Activities related to verifying the effectiveness of actions taken to deal with deficiencies, including:

(i) those actions taken to eliminate, correct or authorise release of deficient S&E work which does not comply with the quality standards;

(ii) those actions taken to eliminate the causes of deficient S&E work and prevent the deficiencies from recurring.

(d) Activities ensuring the continuous improvement of established processes underpinning the issue of S&E reports.

(a) Activities related to verification, validation and monitoring; as carried out in order to assess compliance of S&E work with PCT/GL/ISPE.

All the PCT S&E work is sent electronically from the examiner to his respective Head of Technical Division and to the Head of PCT-Administrative Unit for verification, validation and monitoring.

Once approved, the reports are sent to the applicant and to WIPO.

(b) Processes for measuring, recording, monitoring and analyzing performance of the QMS to assess its conformity with the requirements of Chapter 21 and, if applicable, any other normative reference for the QMS.

A review of randomly selected files is done by considering different aspects linked to Guidelines and Administrative Instructions compliance. It includes either technical aspects (citations, relevant documents, relevant parts, appropriate reasoning, etc) as well as formalities. Depending on the number and nature of deficiencies found, it can be necessary to hold a meeting with the Heads of the Technical Divisions in order to take the appropriate preventive or corrective action. For straightforward questions the action can be directly taken with the examiners.

The QMG reports once per year to the Quality Supervisory Group chaired by the Director of the Patent Department and formed by all the Heads of the Operative Units which should approve or disapprove the reports on the activities of the QMG and will prepare an executive report for the Committee of Direction.

(c) Activities related to verifying the effectiveness of actions taken to deal with deficiencies, including:

- (i) those actions taken to eliminate, correct or authorize release of deficient S&E work which does not comply with the quality standards; and
- (ii) those actions taken to eliminate the causes of deficient S&E work and prevent the deficiencies from recurring.

Periodically (each six months) a report is sent from the different technical units to the QMG on what the current practice is in search and examination, formalities work and administrative tasks, so that the QMG may decide on further actions to be taken. By instructions provided:

- To the examiners
- To the Heads of the Technical Units
- Through the periodic meetings held by the Heads of the Technical Units and the Head of Administrative Unit.
- Through the memorandums for all the search and examining staff, the QMG contributes to achieving and maintaining practice to a uniform quality.

(d) Activities ensuring the continuous improvement of established processes underpinning the issue of S&E reports.

Through the process carried out by the QMG a continuous improvement of process is achieved.

The internal quality assurance system related to search and examination activities is coordinated by the Heads of the Technical Units in connection with the Heads of Technical Divisions, the Head of PCT-Administrative Unit and the QMG.

The head of technical unit ensures in particular that the search and the examination carried out in his/her Unit conform not only to the requirements of the PCT but also with the various directives and regulations in force. Regular meetings are held with the examiners in their units at which particular topics are discussed.

Inter-Units meetings together with the Heads of the Technical Divisions are also held in order to discuss relevant topics to improve and harmonize practice.

Feedback arrangements (Paragraph 21.08)

Give information on arrangements to:

(a) Provide feedback to staff informing them of results of verification, validation and monitoring carried out in order to assess compliance of S&E work, so that:

(i) deficient S&E work is corrected;

(ii) corrective action, i.e. action necessary to prevent recurrence, is identified and implemented;

(ii) best practice is identified, disseminated and adopted.

(b) Accommodate prompt feedback from WIPO, designated and elected Offices; so that potential systemic issues, e.g. recurring deficiencies of S&E work, as identified by these bodies, are evaluated and addressed.

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(ii) best practice is identified, disseminated and adopted.

There is an specific site in the SPTO INTRANET site as well as in the Internet one. In these sites appear information related to general regulation, statistics and results of surveys.

A SPTO set of specific PCT instructions is included and periodically updated in the Examiner's Desk, covering relevant aspects of the PCT procedure, which need special attention.

Finally, there is a continuous communication of results of the quality process to the staff, addressed by the management of each unit. In case of need a circular to all the personnel involved is issued by the Patent Department Director.

(b) Accommodate prompt feedback from WIPO, designated and elected Offices; so that potential systemic issues, e.g. recurring deficiencies of S&E work, as identified by these bodies, are evaluated and addressed.

The SPTO PCT relevant staff has regular meetings with PCT WIPO representatives in order to follow the status of the different projects. Apart from that, there are a number of informal and very frequent contacts.

Communication, Guidance and Responses to Users (Paragraphs 21.06(c), 21.09)

Give information on arrangements to:

(a) Provide communication channels for dealing promptly with enquiries and enabling appropriate two-way communication between applicants and examiners.

(b) Provide concise and comprehensive guidance and information to users (particularly unrepresented applicants) on the S&E process using the website of your Authority, guidance

literature, and other means.

(c) Monitor and react to user needs and feedback, including:

- (i) measuring user satisfaction and perception;
- (ii) handling complaints;
- (iii) correcting deficiencies identified by users;

(iv) taking corrective action, i.e. action to eliminate the cause of deficiencies, in response to recurring or systematic deficiencies identified by users.

(v) taking preventive action, i.e. action to eliminate the cause of potential deficiencies, in response to potential deficiencies or problems identified by users;

(vi) ensuring needs and legitimate expectations of users are met.

(a) Provide communication channels for dealing promptly with enquiries and enabling appropriate two-way communication between applicants and examiners.

The communication channels established in the SPTO between examiners and applicants or their representatives are:

- Telephone: All the forms completed by examiners include their names and telephone numbers. Examiners are always ready to deal with applicants or agents to provide them the necessary consultancy. All examiners have a particular telephone extension, which is equipped with an answering machine and message storage system in case of absence.
- Personal interview: Since SPTO is an open public accessible institution, personal interviews are granted, in most of the cases, without previous appointment subject to examiner's availability. In any case a personal interview always can be held with a previous appointment.
- Mail: Since all forms include examiner's name and address, communication by writing is ensured.
- Fax: SPTO has a fax centralized service. Fax number is included in all communications.
- e-mail: Examiners have their own electronic mail address codified in the following manner: name.surname@oepm.es in order to provide effective electronic communication.
- Mailbox in the web page: Applicants can also use this mailbox in the internet site of SPTO to send their claims, suggestions, etc.
- Videoconference: SPTO offers communication via RDSI Videoconference subject to previous appointment.

(b) Provide concise and comprehensive guidance and information to users (particularly unrepresented applicants) on the S&E process using the website of your Authority, guidance literature, and other means.

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.

Regular sessions of the Innovation and Patents Forum, formed by the main actors of the patent system in Spain, are held periodically since 2002. In those sessions a very important part is dedicated to Quality, specifically in the framework of the PCT.

- (c) Monitor and react to user needs and feedback, including:
 - (i) measuring user satisfaction and perception;
 - (ii) handling complaints;
 - (iii) correcting deficiencies identified by users;

(iv) taking corrective action, i.e. action to eliminate the cause of deficiencies, in response to recurring or systematic deficiencies identified by users.

(v) taking preventive action, i.e. action to eliminate the cause of potential deficiencies, in response to potential deficiencies or problems identified by users;

(vi) ensuring needs and legitimate expectations of users are met.

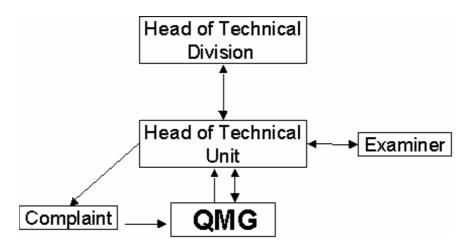
(i) The SPTO is regularly undergoing surveys to measure the quality of the PCT Services as perceived by external users. The surveys consist in: preparation, which includes the analysis of results of preceding studies and making the list of applicants and attorneys who will be contacted for the survey (sample of respondents); analysis by the PCT managers and design of the survey; execution of survey; analysis of results; feedback to Quality process.

Last survey shows the maintenance of the overall satisfaction level of previous years.

Also, through the meetings of the Innovation and patents Forum feedback of the PCT service is received.

As it was stated before SPTO has a suggestion mailbox in the web page.

(ii) Handling of complaints has been developed in order to improve the functioning of the system



Heads of Technical Units are responsible for answering the complaints after the required communication with other groups and QMG maintains its role on the overall supervision.

Mails from applicants or representatives regarding complaints relating to search and examination activities may be directed to different departments (Filing and Information, Patent Department)

In general, the Departments transmit the complaint either directly or indirectly to the QMG (Quality Management Group) which directs it to the Head of Technical Unit or examiner concerned. If not transmitted via QMG, the Head of Technical Unit concerned has to send a copy of the correspondence to QMG.

The nature or content of the complaint may be mere information or statements not always requesting any answer. But, when the content has the nature of complaint expressing an opinion or shortcomings relating to search or examination activities, a reply has to be prepared.

The Head of Technical Unit, if required together with the examiner and/or other experts, studies the complaint and drafts the reply. The Head of Technical Unit is responsible for the technical aspects involved.

In order to obtain a harmonized practice of replying, the draft reply is forwarded to QMG for editorial checking before returning for signature and dispatch.

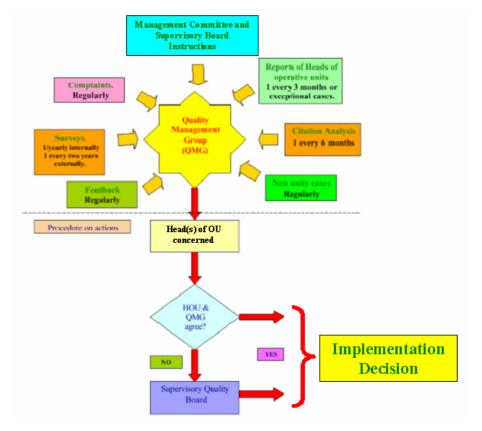
Depending of the nature of complaints the reply is signed by:

- Examiner concerned
- Head of Technical Unit concerned
- Director of QMG
- Head of Technical Division

QMG will advise who should sign, but normally it will be the Head of Technical Unit responsible.

QMG transmits a copy of the outgoing reply to the Head of Technical Division and archives the matter.

(iii), (iv) and (v) The following drawing explains the procedure associated to taken preventive and corrective actions and gathering information:



The Quality Management Group is in charge of gathering all the relevant quality indicators. Based on these indicators, the QMG promote specific actions in cooperation with the Heads of the Operative Units (HOU). It may be that the HOUs could not agree with the analysis of the QMG and do not consider that the proposed actions are really needed. In this case, the Quality Supervisory Board must take a decision on that particular issue.

(vi) As it has been explained above, the SPTO has published a PCT service charter related to control mechanisms regarding timely issue of PCT reports. The PCT Service Charter is in force since January 2005. This service charter includes commitments on timeliness for every single PCT application. According to the rules, the results of the PCT Service Charter will be transparent and public and will be found in the web page www.oepm.es.

INTERNAL REVIEW (PARAGRAPHS 21.10-21.15)

Paragraph 21.10 specifies that, in addition to a "quality assurance system for checking and ensuring compliance with the requirements set out in its QMS" [c.f. Paragraphs 21.03, 21.07], "each Authority should establish its own internal review arrangements to determine the extent to which it has established a QMS based on the above model". This model is set out by Chapter 21 as a whole [c.f. Paragraph 21.02]. Since a QMS which does not contain this provision for internal review would not meet the requirements of Chapter 21, the report under 21.17 should contain at least the information on the extent to which arrangements for internal review required by 21.10 are in place. These are as below.

Required Arrangements for Internal Review (Paragraph 21.10)

The Authority should show that arrangements are in place to ensure that:

(a) An internal review is carried out to determine:

(*i*) the extent to which a QMS complying with the model of Chapter 21 has been established;

(ii) the extent to which the Authority complies with the requirements of its QMS;

(iii) the extent to which the Authority complies with PCT/GL/ISPE.

(b) The internal review demonstrates whether or not the requirements of the QMS and PCT/GL/ISPE are being applied consistently and effectively.

(c) The internal review takes place at least once a year.

(a) Periodically, an internal study on the content of ISR and WO is carried out. Several parameters are monitored:

- Percentage of claims affected either by novelty or inventive step.

- Substantive examinations objections such as in claims, description, etc

As it was previously said, another way to monitor PCT quality is the continuous contact with our costumers (i.e. Patent Forum) and the surveys on the PCT level of satisfaction.

(b) All this information is analyzed by the QMG using statistical studies and doing comparisons with the expected quality parameters. Actions to improve the quality of the PCT performance are taken based on the results obtained.

(c) As it was previous stated, QMG meetings are established every six months and SQG meetings are established once per year.

OPTIONAL INFORMATION UNDER PARAGRAPH 21.17 Guide to Internal Review Arrangements (Paragraphs 21.11–21.15)

Paragraph 21.11 states that 21.12 - 21.15 are "proposed as a guide to the basic components of an internal review mechanism and reporting system", and are thus optional. Authorities may respond to the following points to indicate the provisions they have in place for Internal Review.

The Authority may show that the following arrangements are in place and will be used for the purpose of internal review:

(a) Arrangements providing information on conformity of S&E work; i.e. information from activities related to verification, validation and monitoring, as carried out in order to assess compliance of S&E work with PCT/GL/ISPE [c.f. point (a) under "Quality Assurance" above].

(b) Arrangements providing information on the effectiveness, and the extent of implementation, of the QMS and its processes; whereby it can be established to which extent the QMS complies with the requirements of Chapter 21 and, if applicable, any other normative reference for the QMS.