

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: **European Patent Office (EPO)**

on: **18 December 2006**

Documents referred to in this report:

1. Annual Report of the EPO for 2005
2. EPO Applicants Guide - Part 2

The above cited documents are all available via the EPO's Internet site.

Each Authority must provide information with respect to its Quality Management System (QMS) arranged under the main headings as set forth in this template. The descriptions in this template below each main heading 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.

This template is to be used for a main report under paragraph 21.17 of the PCT International Search and Preliminary Examination Guidelines. Updating reports may thereafter usually be presented in abbreviated format using template T21-18.

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.*

General background information relevant to the QMS

The EPO is the public service authority tasked with examining applications within the legal framework of the European Patent Convention (EPC) and the Patent Cooperation Treaty (PCT). In 2005 the EPO adopted the policy outlined in the document "The Quality mission of the European Patent Office" (See annex 1), and established a Principal Directorate for Quality Management (PDQM) under DG 2 "Operational Support", responsible for implementing a QMS for the examination area and defining quality standards for core products and services; and a Directorate for Quality Audit (DQA) in the PD Internal Audit, reporting directly to the President, responsible for auditing compliance with these quality standards.

The EPO QMS is still in the process of being implemented in this reporting year (2006). It is being introduced in the "examination area" which includes the departments and functions responsible for performing International Search and Preliminary Examination.

Recognised normative reference or basis for quality management system besides Chapter 21

At the EPO ISO 9001:2000 provides the basis for the QMS being implemented and EFQM is a longer term goal for the organisation. Although certification under ISO 9001:2000 is currently not a specific objective, the QMS shall be compatible with this standard.

The following requirements of ISO 9001:2000 will not apply to the EPO QMS for the examination area, for the reasons given below:

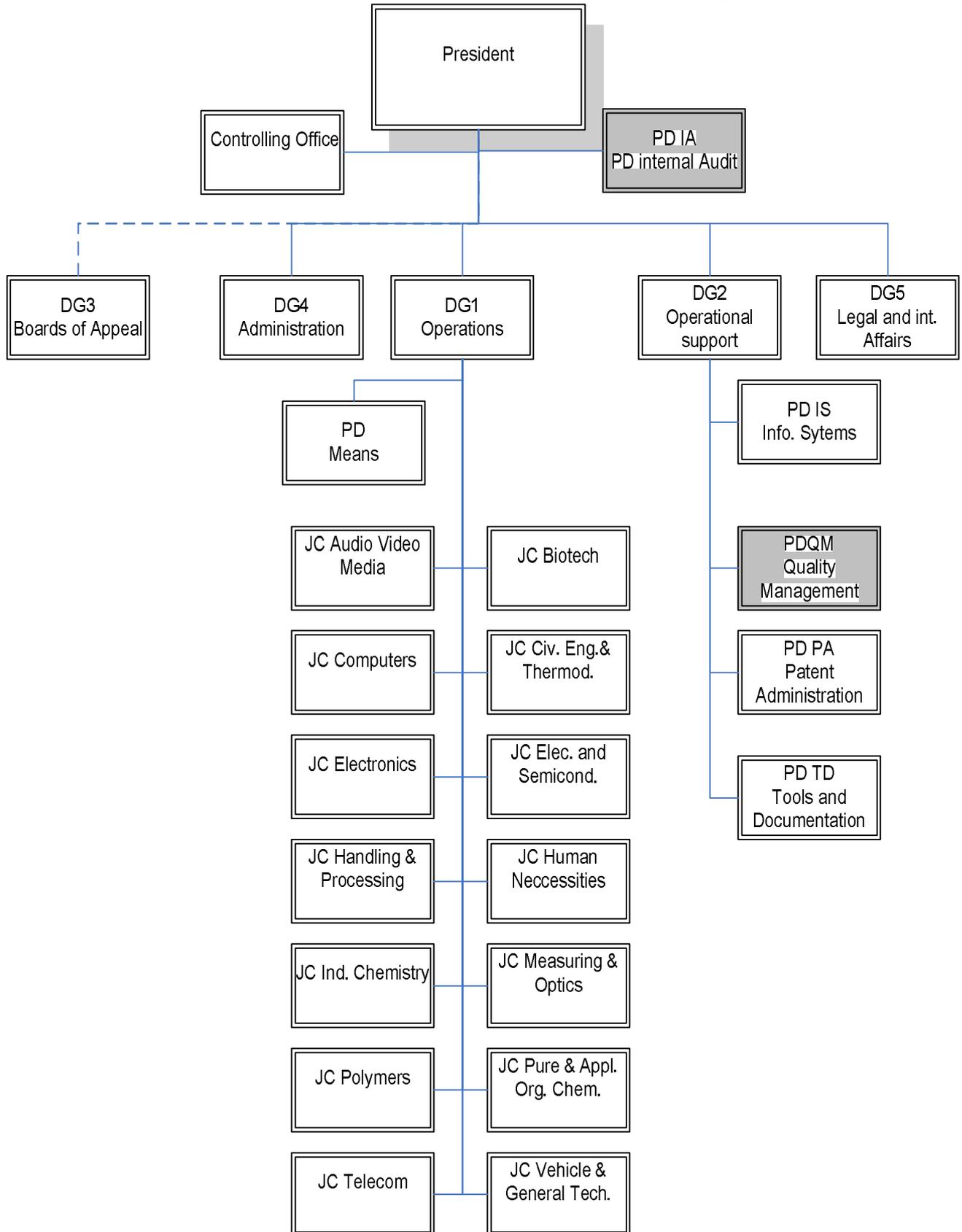
7.3 Design and Development: Deliverables are fully described in the European Patent Convention (EPC), the PCT and their implementing Regulations. Since the EPC and PCT define the statutory and regulatory requirements to be met by the services and products of the examination area, no design or development of such products or services takes place at the EPO.

7.5.3 Traceability: This requires that all elements contributing to the final deliverables can be traced back to their source. This does not apply to products and services of an intellectual nature as delivered by the examination area.

7.6 Control of monitoring and measuring devices: No calibrated measuring devices are used to determine conformity of products of the examination area.

Organigram

The organisational structure of the EPO is shown below. The department responsible for auditing, "PD Internal Audit", and the department responsible for the design and implementation of the QMS, "PDQM", are shown with a shaded background.



The EPO is organised into 5 major units or Directorates-General (DGs).

Directorate General 1 (DG 1) : Operations

This DG is responsible for search, examination and opposition, and is subdivided into 14 sub-units (“Clusters”), broadly relating to 14 different areas of technology. It is complemented by Principal Directorate (PD) Means, which is responsible for DG 1 planning and monitoring.

Directorate General 2 (DG 2): Operational Support

The main role of this DG is to support and facilitate examination work carried out by DG 1. It comprises PD Information Systems (PDIS), PD Quality Management (PDQM), PD Patent Administration (PD Pat Admin), and PD Tools & Documentation (PD Tools). The **examination area** is made up of the 14 Clusters of DG 1, together with PD Tools and PD Patent Administration from DG 2.

Directorate General 3 (DG 3): Boards of Appeal

This DG comprises the Technical Boards of Appeal which examine appeals against decisions of the receiving section (DG 2), examining divisions (DG 1), opposition divisions (DG 1) and legal divisions (DG 5). It includes the Enlarged Board of Appeal which reviews decisions of Technical Boards of Appeal in special circumstances.

Directorate General 4 (DG 4): Administrative and Financial

Deals with financial and administrative processes within the EPO not primarily linked to the patent examination process. DG 4 is also responsible for the publication of patent applications.

Directorate General 5 (DG 5): Legal and International affairs.

DG 5 comprises the legal and international affairs department of the Office, which includes the following departments; European and International Affairs (5.1), International Legal Affairs and Patent Law (5.2), Legal Services (5.3) and the European Patent Academy (5.4).

Organisational units responsible for implementation of the QMS

Principal Directorate Quality Management (PDQM) falls under Directorate General 2. PDQM is responsible for the documentation, implementation and maintenance of the QMS, and reports to DG 1 and DG 2 top management on the extent of implementation and performance of the QMS. PDQM is also responsible for liaison with external parties to obtain feedback and co-operation. PDQM is responsible for promoting the awareness of quality throughout the organisation.

Principal Directorate Internal Audit (PDIA) reports directly to the President. It measures the level of compliance of search and examination work with the EPO quality standards. This takes place according to a Quality Audit plan, prepared by PDQM and approved by the President. The data obtained by PDIA is made available to DG 1 management, and to PDQM for further analysis and correlation with data from other sources.

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.*

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

The Administrative Council has mandated the EPO to establish a QMS under the responsibility of Principal Directorate Quality Management (PDQM). This system is now in place and the details are set out in the appropriate sections of the current document.

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

The quality assurance scheme is described in various internal EPO documents and a Quality Manual is in preparation. The publicly available section will be made available in the course of 2007. The QMS incorporates two quality assurance mechanisms as follows:

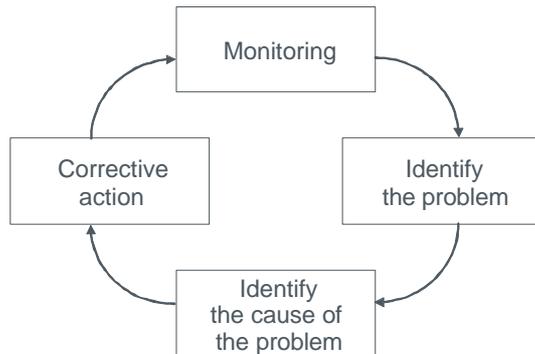
Internal audit of the QMS:

Directorate Quality Audit (DQA), which is independent of all DGs and reports directly to the President, is building up capability for this task. DQA will verify that the QMS complies with the requirements of Chapter 21 and other normative references on an

annual basis. DQA auditors have received some training in ISO 9001:2000. A start on this process will be made in the audit performed by DQA in 2007.

Quality Monitoring and Assessment loops:

Quality assurance at the EPO is based on guidance, monitoring and assessment. These procedures have always been present within the examining area, and have always been based on the principle of the "Quality Loop" shown below.



The steps of monitoring products, services and processes; identifying any problems; identifying the cause of these problems; and taking corrective action; are carried out at all levels of the organisation. The introduction of a formalised QMS has allowed these steps to be aligned, reinforced and supplemented.

Examiners are instructed how to produce "quality at source" by extensive training and work instructions. Line managers support, encourage and assess quality within their units on a daily basis. Search work as well as examination work undergoes monitoring, assessment and, where necessary, correction by the director before leaving the unit.

Many quality assurance activities have been grouped under the responsibility of Principal Directorate Quality Management (PDQM) in DG 2 as part of the function of Operational Support. These include:

- Monitoring Quality

Directorate Metrics and Standards (DMS) is responsible for collecting quality related data and for implementing means for monitoring the metrics data on the quality of S&E work, and for measuring compliance with accepted standards.

- Setting Standards and Providing Guidance:

Directorate Practice and Procedure (DPP) chairs the Practice and Procedure Committee (PPC). This committee sets standards and disseminates work instructions for examiners and administrative formalities officers, such as the Guidelines for examination in the EPO. Other guidance concerning the PCT route, provided by WIPO, is made available to all staff concerned.

- Providing training:

Translation of guidance into daily work is facilitated by adapted training. This is organised and co-ordinated by Directorate Learning and Development (DLD).

- Establishing a structured and documented QMS for S&E work

Directorate Quality Management Support (DQMS) is tasked with consolidating and expanding the existing QMS into a framework compliant with ISO9001:2000

Administrative work and formal examination at the EPO is performed by "formalities officers" who produce "quality at source" with the support and guidance of extensive administrative software systems and with the assistance of the "Fil d'Ariane" application, an extensive on-line database which fully documents all procedures performed by formalities officers. If shortcomings are detected, feedback is given by

line managers, technical directors and examiners. An intermediate level of quality assessment for formalities work, based on structured operational checks, is under development [see response to "Quality Assurance Procedures [Paragraph 21.07]", section (a) below; in particular reference to "Operational Quality Control (OQC)"].

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) 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;**

The Administrative Council of the EPO approves an annual budget before the beginning of a financial year. It is therefore necessary to plan recruitment, investment and production well in advance of this. To do so, The Controlling Office, reporting to the President, uses extensive econometric modelling to prepare forecasts of the expected number of filings and it consults the Clusters to determine the available search and examination capacity so that planning can be undertaken to ensure that the Office can deal with the anticipated workload in the coming five years.

Currently, there are three planning exercises based on the 5-year forecast:

- the Medium Term Business Plan: this is a five year business plan to fix the budget for the next year and to review the situation with respect to the criteria of an internal EPO "Mastering the Workload" strategy document over the next five year period;
- a Revised Plan: this is a one year operational plan which takes the most up-to-date data at the end of the previous year into account to fix the Cluster production targets. It is established at the beginning of the year;

- an Annual Forecast: This is currently carried out in September to assess the possible situation at the end of the current year. It is provided during the year so that necessary actions to achieve the yearly targets can be implemented.

Each of these planning exercises have the objective of ensuring that timeliness-performance and stock levels reach acceptable levels by the end of the planning period under consideration. This requires planning of examiner recruitment and investments, based on realistic workload predictions and productivity figures. Production targets are set in each of the different procedures relevant to this report, i.e. publication of PCT applications; and production of International search reports and IPERs.

Detailed planning is done by each of the 14 Clusters, since each Cluster faces its own particular situation with respect to filing trends, availability of suitable candidates for recruitment, historical stock levels, etc.

A PD Means "Planning Team", made up of PD Means directorates, ensures that the whole planning process for the S&E work performed by DG 1 is coordinated and that the plans are correctly established and aggregated. PD Means also makes the necessary planning tools available to Clusters, organises communication between them and the Vice-President DG 1 (VP1), and conducts analyses with respect to planning on request of VP1.

In conclusion, planning of S&E work is the result of a combined effort of the Clusters, VP1, the Controlling Office and PD Means.

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

Stringent requirements ensure that recruited staff have the necessary technical qualifications and these requirements are rigidly applied during the selection procedure. In 2005, 320 new recruits joined the EPO. They were selected from over 1700 interviewees who in turn were chosen from some 22 000 applications.

The requirements used to select suitable examiners, besides the statutory requirement for nationality of an EPO member state, include:

- a full university degree in engineering or a science;
- the ability to understand applications in all three of the official languages of the EPO (English, French and German);
- a genuine interest in technology, an eye for detail and an analytical mind.

Where possible, suitable applicants fulfilling the above technical requirements and having work experience in industry are recruited.

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

EPO examiners are recruited according to stringent language requirements. The need for language training is assessed during job interviews. A candidate must demonstrate an excellent knowledge of one of the official languages (English, French and German) and ability to understand the other two. The office provides additional language training which, together with multilingual technical libraries and biennial

assessment of language proficiency by Directors, ensures continuous improvement of examiners' language skills.

(b) Adequate quantity and skills of administrative staff to support S&E.

The medium term business plan [see Resources - infrastructure (Paragraph 21.05 (a) (i) above] also addresses the level of administrative staffing. Administrative staff is trained by a "Knowledge Management Team" (KMT). The training package consists of classroom modules and on the job training. Job rotation and targeted training ensures that the administrative staff member acquires knowledge of several procedures within the office throughout their career. Selected staff will specialise in various key procedures e.g. PCT formalities work.

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

All staff are equipped with fully networked independent work-stations to support the search and examination process; in particular software is provided for establishing International Search Reports (ISR), Written Opinions and International Preliminary Examination Reports (IPER) and can be used in a combined way to issue the ISR and WO-ISA.

Computer-based search of the documentation:

EPOQUE is being rebuilt with a view to enhancing the system's search capabilities and performance. In 2005 a total of 236 million documents were viewed, 25% more than in 2004, and EPOQUE had 4 950 users per month at the EPO and in member states' patent offices.

In the year under review the Office launched a new project to develop EPODOS (EPO DOSSier), an integrated tool that will enable a patent examiner to prepare the written opinion and the search report simultaneously. The project is now in the user interface design phase, due to be completed by the end of 2006.

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

The provision of documentation extends well beyond the required PCT minimum.

Documentation data resources

The number of electronically searchable patent documents in the EPO's main search database rose to around 53.2 million in 2005. The number of facsimile digitised documents covering patent and non-patent literature rose to 62 million, an increase of 6.7 million documents. Special efforts were made to acquire new databases in the fields of telecommunication standards and traditional knowledge.

In the context of bilateral co-operation with Asia, efforts were made to add ASEAN patent data to the Espacenet database, and access to Chinese technical information was significantly improved: 1.3 million Chinese patent documents were added to the EPO databases and to Espacenet, including a database of traditional Chinese medicine.

Documentation data management and quality

The number of documents in the bibliographic master database rose by 3.4 million items.

The DOCAREA Rebuild project passed three major milestones in 2005: continuous data loading and online correction is now possible; the master classification database can handle data from offices using the new eighth edition of the International Patent Classification (IPC8); and the Office's main search database can be updated daily (instead of weekly), enabling new patent documents to be available via the EPO's search engine for electronic patent searching (EPOQUE) or Esp@cenet® on the day of publication.

The EPO citation database contains information on patent and non-patent literature cited in applications and publications; it currently contains 14 million references relating to 5 million applications or publications. In 2005, quality control and correction work on 4.6 million new cited documents resulted in 314 000 manual corrections.

Classification

One of the Office's core activities is the classification of patent documents using its own European Classification system (ECLA), an expanded version of the International Patent Classification. ECLA comprises about 130 000 classification groups to allow for fast and systematic access to search documentation in all areas of technology. It can also be used for Espacenet searches, and is distributed to external subscribers on CD-ROM.

One major activity in the classification area in 2005 was the technical implementation of IPC reform to make the EPO ready in time for the new IPC8's entry into force at the beginning of 2006.

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

The joint DG 1–DG 2 "Practice and Procedure Committee (PPC), chaired by PDQM Directorate Patent Practice (DPP), is the managerial body responsible for keeping work manuals for examining staff up-to-date and ensuring their effective distribution.

DG 2 PD Patent Admin. is responsible for compiling, updating and disseminating work instructions for administrative staff. This is done by a dedicated "Knowledge Management Team" (KMT) which is also responsible for training staff and updating "Fil d'Ariane", an online reference tool that describes in detail all work procedures performed by administrative staff.

These must include explanations of:

(i) quality criteria and standards;

Quality criteria and standards are described in "The Quality Mission of the European Patent Office" (See annex 1) and have been communicated to all staff.

(ii) descriptions of work procedures;

All S&E staff are provided with up-to-date legal texts, guidelines and work instructions, including electronic (fully searchable) and paper copies of the PCT and PCT/GL/ISPE. All staff have access to the WIPO internet site which also contains this information.

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

All staff members are taught and instructed to adhere to the work procedures described in the guidelines and internal instructions. If deviations from recommended practice become evident, these are brought to the attention of the PPC. In response, the PPC issues a "Practices and Procedure Report". This is a reminder to staff explaining why the deviating practice should be avoided and how to correctly apply the existing guidance.

A "Quality Board", similar in structure to the PPC, is the joint DG 1-DG 2 managerial body dealing with quality issues. It will become operational in December 2006, complementing the existing guidelines and instructions with documented quality management procedures. These procedures will focus on organizing and controlling the production and quality-related processes. Where required these mandatory quality procedures will make reference to the existing guidelines and instructions.

(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.*

PDQM Directorate Learning and Development (DLD) is in charge of meeting this requirement.

Continuous personnel training in all areas is the key to success of quality management of S&E work at the EPO.

A learning and development plan is in place for all examiners.

The initial training period lasts three years and consists of a mix of classroom training and on-the-job training under the supervision of a coach. Different coaches are assigned over the initial training period. Evaluation of the acquired skills of the examiner is done by the Director with input from the coach(es).

Courses for acquiring specialised skills are available and are offered at the discretion of Directors, according to need and the examiners position on a planned career path. Records of the skills and competences so acquired are kept in a central database, which allows examiners to be deployed effectively on different tasks.

In 2005, apart from technical instruction for the examining area, well over 1 300 seminars on languages, professional knowledge, IT, communications, human relations and management were organised for more than 11 000 participants, with managerial topics accounting for around 5% of all training.

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

The medium term business plan and forecasts by the Controlling Office [see Resources - infrastructure (Paragraph 21.05 (a) (i) above] also address the provision of adequate tools and documentation [see (d) above] and are the basis for ensuring that appropriate buildings and infrastructure are made available. Providing the buildings and technical infrastructure is the responsibility of DG 4, the Directorate General responsible for administration. Budgets for these major resources are submitted to the EPO Administrative Council for discussion, amendment and approval. This is the body ultimately responsible for the ensuring that sufficient resources are made available to the EPO to fulfil its tasks.

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.*

Time limits concerning S&E work undertaken as an IA are integrated in, and automatically monitored by, fully computerised administrative systems.

Automated procedures allow for flexible deployment of administrative staff to meet timeliness criteria. Publication dates of PCT applications, as well as planned issue dates for S&E work, are monitored so that administrative staff and examiners can provide data for publication in due time and so that they can prioritise S&E work for International applications. If delays arise, reminders are automatically issued to the staff concerned, followed up by line-manager checks. Monitoring facilities are enhanced by the "Mega-list" application introduced in 2006 by PD Means. This generates stock overviews for Principal Directors, Directors and examiners, which facilitate the setting of priorities and meeting of commitments.

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

The detailed overviews of the Mega-list application allow monitoring and management of backlogs. PD Means also provides other tools used by Management to monitor fluctuations in demand and set priorities between the work required for different procedures: PCT, EP, or National applications; search examination, or classification work. Under BEST, examining and administrative staff are switched between search and examination work to help deal any with fluctuations.

An internal EPO document describes the "Mastering the Workload" program which shows in detail how the office attacks the current workload in the short term and presents a strategic approach for the long term.

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.

Each DG 1 Cluster is divided into Directorates. Directors are responsible for the quality of S&E work produced in the Directorate under their responsibility. All S&E work produced in these units is signed out by the Directors.

User Satisfaction Surveys conducted are by Directorate Metrics and Standards (DMS) of PDQM in DG 2 to gather data on the perception of users regarding the following aspects of all S&E work:

- thoroughness of the search
- clarity of the search report
- coverage of the independent claims
- coverage of non-patent literature
- consistency of the search reports
- delivery time of the search reports
- formal aspects of the search procedure
- relevance of documents cited as X
- relevance of documents cited as Y
- relevance of the passages cited
- understanding by the search examiner.

These surveys are carried out annually to assess compliance of S&E with i.a. PCT/GL/ISPE. Results are used to validate the processes leading to output of S&E work.

Pilot projects for Operational Quality Control (OQC) were run in four Clusters in 2005. Results were evaluated in 2006 and a concept for full implementation was developed. This involves specially nominated experts in broad technical areas ("Quality Nominees") who sample and check search reports and written opinions. The results provide a statistical picture of the level of compliance of the S&E work of each Cluster, and are used to pinpoint training needs and to further validate the work processes involved. Implementation of Cluster Level OQC (CLOQC) has started and the first data are expected in April 2007.

Pilot projects have been run to assess the quality of the work performed by administrative staff, on the same basis as OQC for S&E work. In 2007 those pilots will be extended to all patent-related administrative procedures in the office. The pilots that have been concluded will be evaluated, adapted and implemented.

(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.

In 2006 DQMS carried out a gap analysis of the QMS with respect to the ISO9001 standard and the requirements of Chapter 21, and identified several areas for action. Members of the Directorate Quality Audit (DQA) have been trained as Quality Auditors and are now qualified to carry out QMS audits against ISO9001 standard and the requirements of Chapter 21. The start of this internal audit work is foreseen for 2007, and will be carried out by DQA who will continue to draw up the annual Quality Audit Report for the President.

(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;

DG 1 directors are responsible for the quality of the S&E work in their units. They initiate corrections and authorise the release of this work.

If any corrections are appropriate in response to a complaint received about a particular application, then this correction is initiated by the director in cooperation with Complaints Management, which falls under the DG 2 Directorate Quality Management Support (DQMS).

Deficiencies in the formal treatment of S&E work are corrected under the supervision of Administrative Staff Line Managers who manage a number of formalities officers. Central Administrative Units, made up of skilled administrative staff who act as specialists in various procedures, e.g. PCT work, provide specialised advice and expertise.

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

DG 1 directors are in the most favourable position to steer examiners' practice. Regular biennial reporting by Directors on examiners' performance includes assessment of the quality of the individual examiner's work and their aptitude for the tasks assigned to them.

If causes of deficiencies are systematic and go beyond individuals or beyond a single Directorate, the Practice and Procedure Committee (PPC) chaired by DG 2 Directorate Practice and Procedure (DPP) will issue guidance in the form of Internal Instructions. In addition, adapted training may be developed by the DG 2 Directorate Learning and Development (DLD) .

Complaints Management under DQMS harmonises the treatment of any external complaints received about particular applications or aspects of S&E work. The complaints are systematically analysed by DQMS, who detect any recurring deficiencies. These are referred to the PPC via DPP, which will then issue further guidance to examiners if necessary.

The procedure for initiating corrective actions in the formalities area is similar to that for examiners.

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

Various working groups and committees are active to improve the processes related to the issue of S&E reports. .

- The Practice and Procedure Committee (PPC) supported by the Directorate Practice and Procedure (DPP) improves examiners' practice in general.
- The Learning and Development Committee (LDC) supported by Directorate Learning and Development (DLD) improves the training and knowledge transfer for examining staff
- Documentation and tools for S&E work are reviewed by a number of joint DG 1/DG 2 managerial bodies which discuss problems and initiate solutions. These include JOBSIR(JOint Board for Scientific Information Resources), representing DG 1 operational S&E directors and DG 2 PD Tools / Doc directors responsible for developing the tools supporting S&E work; ASCOT (Advisory Steering COmmittee for Tools) which identifies priorities; and CEPAS (Committee for Electronic PATent Searching), which evaluates suggestions from examiners for improvement of S&E tools and initiates corresponding projects as appropriate.
- Project Boards, set up according to Prince2™ project management methodology, operate under a joint DG 1-DG 2 steering committee for the Business Process Area of Patent Granting and Examination (BPA-PGE). They run projects to improve established processes and infrastructure e.g. as recommended by the above managerial bodies. These include EPODOS (EPO DOSsier) developing an integrated S&E interface for examiners linking all aspects of work done on a particular application; and CASPER (Computer-Assisted Search Process Extraction and Recording), launched in 2006 to provide examiners with an electronic tool to support the generation of a record of the search process for every application treated by examiners.
- Knowledge Management Teams (KMT), set up under DG 2 PD Pat. Admin., are charged with developing and improving teaching methods and training for administrative staff.
- Cluster Level Operational Quality Control
The Cluster Level Operational Quality Control described under 21.07 (a), above, will provide quarterly reports to DG 1 management on the most common deficiencies identified and this will provide a trigger for identification of the causes. The Quality Board will be responsible for ensuring that appropriate corrective actions are documented, undertaken, and the effects monitored.

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;

(iii) 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.

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;

All staff members whose work has been subject to verification are informed about the outcome and are asked to perform any necessary corrections.

Verification of S&E work is conducted by:

- Directors, for search and examination work and formalities officers for procedural issues.

- The Operational Quality Control (OQC) system introduced in 2006 [See response to Quality Assurance Procedures [Paragraph 21.07], section (a) above] involves direct feedback from the Quality Nominees to the responsible member of staff.

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

Major initiators for corrective action are line managers, OQC, User Satisfaction Surveys and Complaints Management. Staff are also encouraged to spot systemic errors and to suggest possible solutions as triggers for corrective action, for example by a Presidential Awards Scheme. PDQM monitors and reports on the implementation of these actions.

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

Successful and efficient corrective actions are translated into guidelines and internal instructions for S&E by the PPC. These become the control documents for future internal processes. The PPC may also propose changes in legislation.

(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.

PDQM liaises with WIPO, designated offices and elected offices on quality issues and complaints via consultative bodies like the MIA and through ad-hoc visits, Remarks and comments from these parties are used as input for internal corrective action as necessary.

The EPO holds regular meetings with the Swedish and Spanish Offices. Working groups have been set up between the three offices under the auspices of the Permanent Committee on the Harmonisation of Search Activities (PCHSA) to study search practice and procedure, search tools and methods, training and the exchange of examiners as well as to monitor search quality.

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 telephone number and name of the examiner in charge of the application is given on all written communications with applicants . Examiners are specifically instructed to grant telephone interviews with applicants.

- (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.*

The following means and resources are in place to fulfil this requirement:

- The office's EPO-line® internet application allows unrepresented patent applicants, attorneys and other users to conduct their PCT business with the EPO electronically in a state-of-the-art secure environment.

- The EPO-line® homepage www.epoline.org provides telephonic and e-mail access to a Customer Support helpline¹ in The Hague administered by Procedural and Technical Support (PTS) under PD Pat. Admin.
- The EPO internet site www.european-patent-office.org features a contact button providing links and direct communication to the EPO, including EPO Customer Services in Munich². The EPO site also provides guidance and brochures for download by users such as the Guide for Applicants, part 2, which specifically deals with the PCT procedure before the EPO, and links to related IP internet sites (including WIPO).
- The EPO Official journal
- The European Patent Academy, run by DG 5, provides assistance and training to national offices
- A regular EPO presence at international and national IP events

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

(i) *measuring user satisfaction and perception;*

Annual User Satisfaction Surveys of search work are part of an expanding program to monitor and react to user needs [see response to Quality Assurance Procedures (Paragraph 21.07) (a), above]. Other aspects of this program which have been implemented are

- Organising regular conferences with users of the patent system, e.g. "Quality Matters", held in The Hague on 21 and 22 November 2005
- Conferences with applicants and representatives under the "Partnership for Quality" scheme, which aims to increase the quality of incoming work e.g. by encouraging clear and concise drafting of applications, but also to provide a forum for users of the system to raise quality issues with the EPO.

(ii) *handling complaints*

The EPO has a fully established procedure for dealing with complaints regarding S&E work. The procedure is administered by Complaints Management under DQMS [see response to "Quality Assurance Procedures [Paragraph 21.07]", sections (c) (i) and (d) above] and incorporates all the requirements listed in points iii) to vi) below.

(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.*

¹ (The Hague Customer Support, Monday to Friday, 08.00-18.00 hrs CET, Tel: +31 70 340 45 00)

² (Munich Customer Services, Tel: + 49 89 2399 4636)

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) *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*

A gap analysis of the current EPO QMS versus the requirements of Chapter 21 was carried out by the DQMS [see response to "Quality Assurance Procedures (paragraph 21.07)," section (b) above]. A review will take place in 2007.

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

An audit of the implementation of the QMS is planned for 2007. Auditors in DQA have been trained to carry out this task [see response to "Quality Assurance Procedures" (paragraph 21.07), section (b), above].

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

As the implementation of the QMS has not yet been investigated a picture of the extent of compliance of the office cannot be given. The assessments done on the S&E work demonstrate the extent to which the EPO 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.*

This part of the review concerning the implementation of the QMS will be conducted in 2007.

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

It is intended to perform the review on yearly basis starting from 2007 onwards.

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.

(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].

Results of user satisfaction surveys are reviewed with top-management and Cluster management. The results of the Operational Quality Control at Cluster level will be documented and reported upon in the course of 2007.

(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.

The documented part of the QMS as well its actual implementation throughout the organisation will be investigated in 2007 by the Directorate Quality Audit (DQA) under PD Internal Audit. Their findings will be presented in a report to top management. This report will be made every year to provide clear guidance on the management decisions needed to ensure that the requirements of PCT/GL/ISPE, Chapter 21 in particular, are consistently met.

Annex 1**The Quality mission of the European Patent Office**
“Strive to excel”

The productive use of knowledge has become essential for a successful economy. This requires effective management of innovation, competition and risks. There is a growing realisation that the patent system enables the European economy to do this, for the benefit of society.

As the public service authority tasked with examining applications within the legal framework of the European Patent Convention and the Patent Cooperation Treaty, the EPO aims to support innovation, competitiveness and economic growth for the benefit of the citizens of Europe by adding value to the knowledge economy through a unified, predictable patent process. To achieve this mission the EPO strives to set patent standards which respond to the needs of European society and to establish a global benchmark for best patent practice. Delivering quality is essential to this. As to the Boards of Appeal, the independent and juridical nature of their activity has to be respected.

Quality is an ongoing activity which must be sensitive to changes in the economic environment and society's perceptions. It involves the whole Organisation and needs the support of all involved in the patent system to succeed. The EPO commits to build on the competence, professional pride and personal responsibility of its staff and to cooperate with all concerned to maintain a quality culture that enables excellence. In such a context, striving to excel must also involve enabling others to excel.

The following principles are at the forefront of the EPO's quality mission:

- Legal certainty: Providing a single procedure for the timely grant of patents which ensures that the rights granted are commensurate with the contribution made to technology;
- ! Service: Reliability and flexibility based on a balanced understanding of the needs and values of European society delivered through the sharing of knowledge among a network of professionals;
- ! Openness: Willingness to be transparent and to publish insights and facts;
- ! Continuous improvement: A permanent commitment to improve thoroughness, consistency, transparency, fairness and timeliness.

In pursuing these principles the Office shall build on the culture of quality and excellence that has established its reputation. The Office will encourage its staff and the system's users to take their own responsibility towards quality and will maintain a total quality management system to ensure that its quality mission is achieved.

The EPO and each of its staff strive to excel