PATENT COOPERATION TREATY

Common Quality Framework for
International Search and Preliminary Examination

Supplemental Report Under Paragraph 21.18 of the PCT International Search and Preliminary Examination Guidelines

by: **European Patent Office (EPO)**

on: **January 2010**

Date of main report and	18 December 2006 (21.17 Report)
any supplemental reports to	21 December 2007 (21.18 Report)
which this is a supplement:	January 2008 (21.18 Report)

No further documents are referred to in this report.

As a result of our most recent internal review under PCT/GL/ISPE paragraphs 21.10-21.15, this Authority has made modifications to its Quality Management System (QMS) as discussed below.

The modifications are given with reference to the sections of the template for responses to PCT/GL/ISPE Paragraph 21.17 to which the changes relate.

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

Changes made to the EPO QMS in 2009 which relate to the requirements of PCT/GL/ISPE Chapter 21, are as follows:

- The CL-OQC methodology (Cluster-level Operational Quality Control) was extended by implementing cross-site checking in most Joint Clusters (JCs) between Munich, The Hague and Berlin of DG1 (Operations).
  See response to '21.03(b); '21.07(a), (d) below

- Extension of the PA-OQC methodology (Patent Administration Operational Quality Control) for patent search and granting administration and formalities in the DG2 Principal Directorate (PD) for Patent Administration (PD Pat. Admin.). See response to '21.03(b).

- A pilot for classification operational quality control (Class-OQC) on the basis of the CL-OQC methodology was started and will be evaluated next year. The results of this evaluation will be used to decide how to extend the method to more fields in 2010.

- The MAC (Management Advisory Committee) of the EPO decided to proceed with a project to achieve ISO9001:2008 compliance. A project board was set up under the Prince2 project management methodology. The project initiation phase has commenced.

- The office implemented MSP (Managing Successful Programmes) to ensure oversight and to avoid conflict of numerous programmes and projects running in parallel.

- The EPO's Strategic Renewal Process (SRP) is an ongoing process to help make the Office fit for the challenges it is facing. This process is divided into different programmes and projects.

- One activity under SRP is the IP5 programme launched by the five major Offices (EPO, USPTO, SIPO, KIPO and JPO) in May 2007. The vision of the IP5 programme is improved global co-operation so as to *eliminate unnecessary duplication of work among the IP5 Offices and to enhance patent examination efficiency and quality.* One of the ten foundation projects aims to provide Common Rules for Examination Practice and Quality Control. This project is led by SIPO.

- A further SRP activity is "Raising the bar" (RTB). It focuses on internal practice, legal aspects and external practice. The latest development concerned proposals to amend

Rules of PCT. At the 40th session of the Assembly of the PCT Union (PCT Assembly) held in Geneva between 22 September and 1 October 2009, approval was given to amendments to Rules 46.5 and 66.8 PCT as proposed by the EPO at the last Meeting of International Authorities

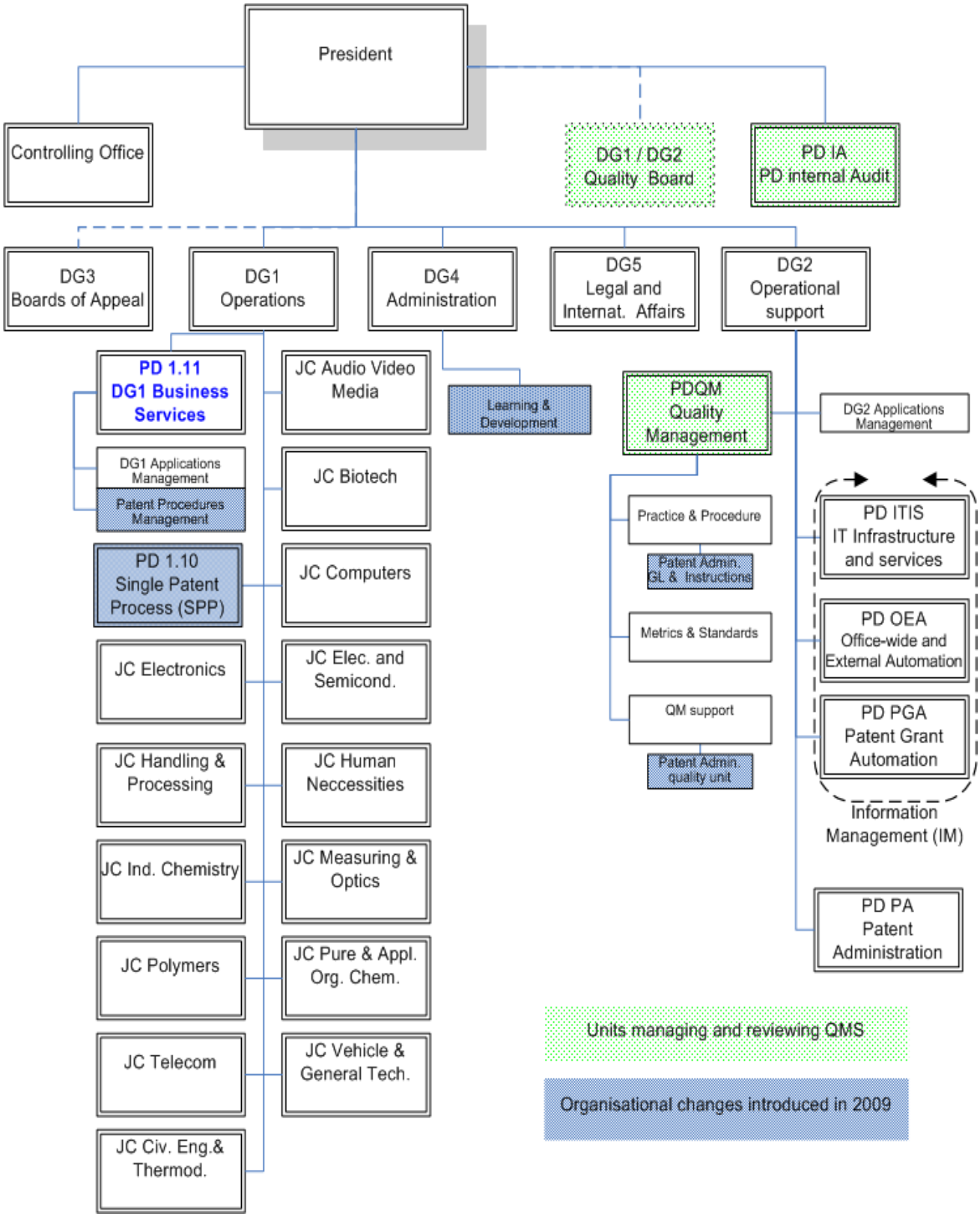
- An additional SRP activity is "the Single Patent Process" (SPP). It focuses on the EPO's vision of the future and the implementation of a highly efficient patent process. It aims to ensure that the initiatives developed support quality assurance in the future including the integration of more plausibility checks in automated processes and supporting tools.

- Organisational changes in DG1 and DG2 enhancing provision and support of tools for search and examination work (S&E).

  See organigram and ' 21.05 (c) below.

  - The EPO centralised the relevant units responsible for developing and implementing a QMS by moving the quality unit PD Patent Administration to Directorate Quality Management Support in PD Quality Management (DG2).
  - The EPO also centralised the departments responsible for establishing Guidelines and instructions to administrative staff by moving the relevant unit PD Patent Administration to the search and examination equivalent, Directorate Practice and Procedure in PD Quality Management.
  - The EPO centralised its training departments under Principal Directorate Human Resources in DG4 in 2009.
  - DG1 operations created a new directorate Patent Procedures Management which assures the maintenance of the procedures where the responsibility lies with DG1.

Organigram January 2010



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) **- Unchanged in 2009** *;*

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

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

- CL-OQC (Cluster-level Operational Quality Control) now includes checking of work across the three sites of DG1 Operations (Munich, The Hague, Berlin). The aim is to identify any substantive site-related differences in practice and to ensure harmonisation of working procedures. Corrective action is taken - where necessary - to ensure that work is produced to the same standards at each site. To achieve this goal around 1% of the whole production is checked across sites and 5% on-site.

- Extension of the PA-OQC methodology (Patent Administration Operational Quality Control) for patent search and granting administration and formalities in the DG2 by checking the process of EP search non-unity. Next year will see a focus of the operational quality control on the procedures PCT search non-unity and receiving section for WIPO.

- The Class-OQC (Classification Operational Quality control) pilot project aims to check classification on all incoming documents and dossiers at the time of search by an experienced classifier called a - mainly "Gérant" who traditionally administers the classification practice in a given field. The aim is for the Gérant to document classification practice and check the work of other classifiers in the team, performing correction and initiating corrective action when necessary.

- Raising the bar (RTB) is a domain under SRP focusing on Internal practice, legal aspects and external practice. Amendments to Rules 46.5 and 66.8 PCT as proposed by the EPO were agreed at the last Meeting of International Authorities.

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: **- Unchanged**

(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. **- Unchanged**

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

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

(e) Provision of up-to-date work manuals. These must include explanations of: **- Unchanged**

(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.

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

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

(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.

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)

- The continuation of the CL-OQC in-process checks on-site and across sites in 2009 (see 21.03(b) above) allows the office to quantify the extent of compliance of S&E work with PCT/GL/ISPE by sampling during the production process. A dedicated sampling, checking and reporting procedure provides each JC with six-monthly reports on the nature and extent of deficiencies of S&E work performed under the PCT.

- In-depth post-production checks on a statistically significant sample of examination and search products (750 and 350 respectively) were carried out by Directorate Quality Audit (DQA) of PD Internal Audit in 2009. The results indicate the extent of compliance of the search and examination products produced by the office as a whole.

- The office intends to make a record of the search process, traditionally called the "Compte Rendu de Recherche" (CRdR), mandatory in 2010. Internal instructions for recording searches in the CRdR are in preparation.

(b)

- A Quality Management Review was held in July 2009 according to the Quality Management Standards set out in ISO 9001:2008. Such reviews are held as regularly scheduled events within an organisation, with top management convening to review the performance of its quality management system against organisational goals and objectives. Issues found during this review will be followed up.

(c) i)

- Unchanged

(c) ii), (d)

- A total of 13137 applications were checked under CL-OQC during 2009, 1844 of these were checked across sites and 4283 of these filed under the PCT.

- A harmonised approach ensuring corrective action for S&E work on the basis of CL-OQC results across all JCs was developed by the DG1 / DG2 Quality board which was assisted by Directorate Learning and Development in creating field- specific training on clarity objections based on CL-OQC findings, as well as training material dealing with the issue of added subject-matter (See 21.17 below) was continued in 2009.

- An extensive process-audit of the entire CL-OQC procedure was performed in 2008. Recommendations for improving the process and in particular its documentation were addressed and implemented in 2009.

- A pilot for Classification Operational Quality Control (Class-OQC) was started in November 2009 for the duration of 6 months. In all, a total of 1100 documents and dossiers in six pilot fields (two from Chemistry, two from Electricity/ Physics, and two from Mechanics) will be checked by experienced classifiers during the six-month pilot phase. It is planned to investigate how to expand this OQC after evaluation of the pilot in 2010.

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. **- See '21.07(c), (d) above**

(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. **- Unchanged**

(a)

- Presentations on operational quality control findings for 2008 and 1st half of 2009 have been prepared and have been presented to all operational management teams. These presentations were cascaded down to all examination staff in 2009.

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. **- Unchanged**

(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. **- Unchanged**

(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.

- User Satisfaction Surveys were carried out between 2007 and 2009 on the search and examination work of all fourteen Joint Clusters.

- Results were presented to the management teams of eight of these Joint Clusters in 2008. Results for the remaining 6 clusters were presented in 2009.

(c) (iv)

The eGate project was launched to automate Front End procedures, inter alia to increase the quality of the bibliographic data stored in EPO databases.
The EPO selected PCT procedures to start with, as major gains could be foreseen here and because the EPO anticipates receiving paper search copies from various PCT/RO's for some time to come. Since July 2009 all PCT search copies have been processed through eGate which has reduced processing time.
Currently, the received PCT search copies are subject to indexing, scanning or soft scanning, respectively, and uploading into EPO databases as tiff images. During this upload, the PCT Request Forms are selected automatically and sent to an external contractor to OCR 13 critical data fields. When returned an automatic check is performed on these critical data fields for completeness. If no errors were discovered the respective EPO bibliographic data base is uploaded automatically. Where errors are discovered, corrections are made manually before upload.

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.

- The first review according to Chapter 21.10 carried out in 2007 identified actions necessary to ensure that (a), (b) and (c) are consistently met. The status of these was reported to top management in June 2008 (see response to '21.07(b) above).

- An Internal Review was held in July 2009. Top management convened to review the performance of its quality management system against organisational goals and objectives. Issues found during this review need follow up. One of these issues concerns the Office's Quality Policy which will be updated to reflect the Office's new Mission. Another of these issues concerns the Office's Balanced Scorecard in which the Key Performance Indicator currently fails to reflect the results of User Satisfaction Surveys.

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.

- The DG1/DG2 Quality Board met four times in 2009. It decided to align the checklists on clarity for CL-OQC and Quality Audit. A critical review of results generated by PA-OQC, the User Satisfaction Survey (USS) and the complaints received by the office took place and fields of improvement were identified.

- CL-OQC results highlighted the need for corrective actions in some areas of examination work, notably clarity of the claimed subject matter. The DG1/DG2 Quality Board launched these in 2008, implemented them in 2009 and will monitor progress in 2010.

[End of report]