

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 2008**

Date of main report and
any supplemental reports to
which this is a supplement: 18 December 2006 (Paragraph 21.17 Report)
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Documents referred to in this report:

1. "Establishment of a DG 1/DG 2 Quality Board and Quality Working Committees for Search and Examination and for Patent Administration",
VP1 / VP2 note to staff published on Intranet, 22 June 2007
2. "Quality Management Review - PCT Chapter 21"
Drafted by DQMS, 13 Dec 2007

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 revised 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:

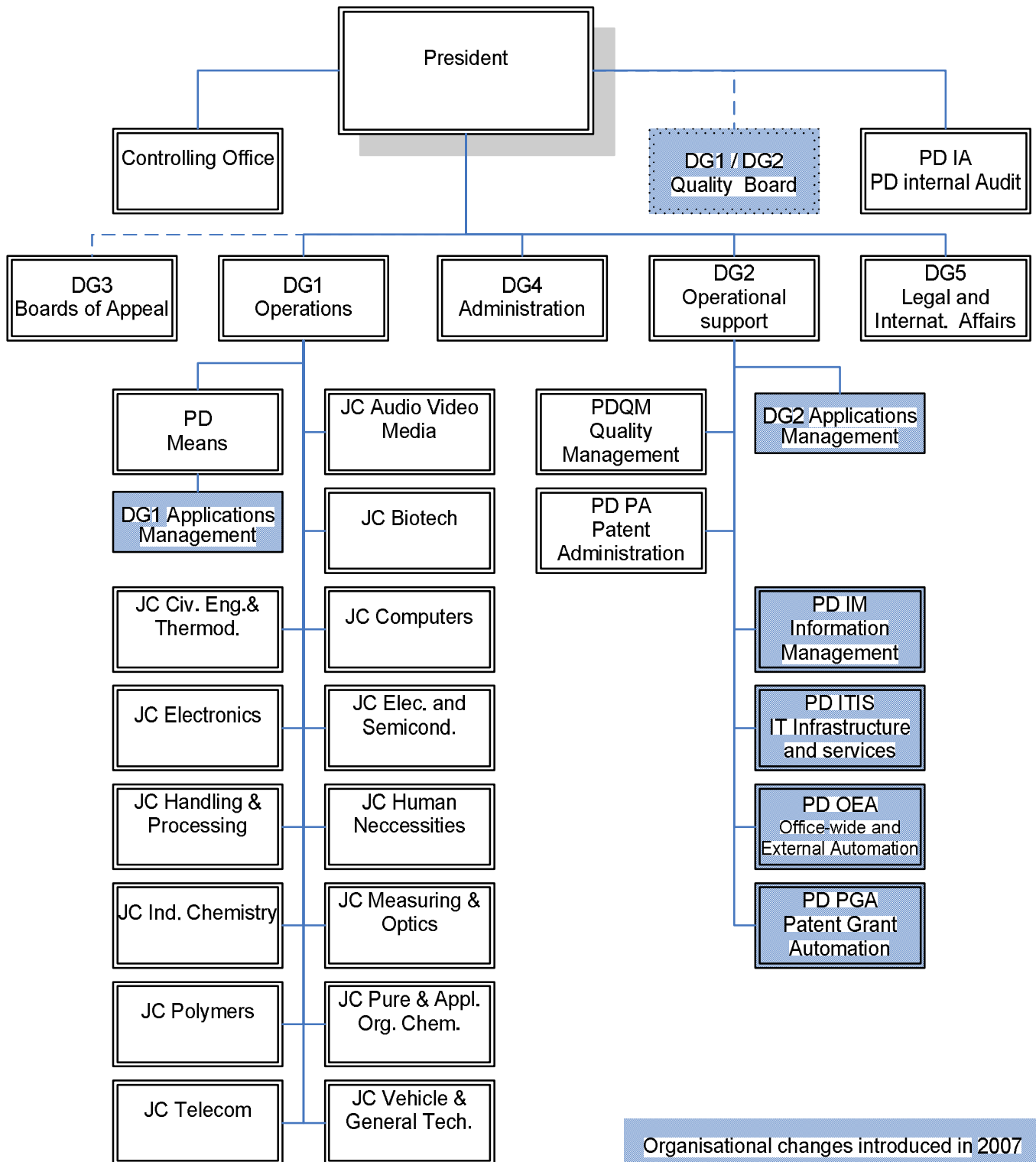
- *Recognised normative reference or basis for quality management system besides Chapter 21, e.g. ISO 9000.* - **Unchanged in 2007**
- An organigram showing at least the organisational units responsible for implementation of the Authority's QMS. It could be referred to in the rest of the report, as necessary.

General background information relevant to the QMS

Changes made to the EPO QMS in 2008 which relate to the requirements of PCT/GL/ISPE Chapter 21, are as follows:

- Implementation of the CL-OQC methodology (Cluster-level Operational Quality Control) for examination work in all 14 Clusters of DG1 (Operations).
See response to ' 21.03(b); ' 21.07(a), (d) below
- Implementation of the PA-OQC methodology (Patent Administration Operational Quality Control) for patent granting administration and formalities in the DG2 Principal Directorate (PD) for Patent Administration (PD Pat. Admin.).
See response to ' 21.06a, b); ' 21.07(a) below
- 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.
- Establishment of a high level, joint DG1/DG2 decision-making body for Quality Management ("Quality Board", Ref. 1).
See response to ' 21.11-15 below

Organigram



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 2007** ;*
- (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.

2007 saw the implementation of the CL-OQC methodology (Cluster-level Operational Quality Control) for examination work in all 14 Joint Clusters (JC) of DG1 Operations.

CL-OQC introduced changes to working procedures for administrative and examining staff. These enabled random sampling of search and examination work during the production process. About 6% of S&E production was checked according to on-line checklists by examiners designated as Quality Nominees. Quality nominees are selected for their technical and legal competence and interpersonal skills, and at least one is present in every operational directorate. 250 Quality Nominees were trained in 2007.

Quality Nominees are instructed to provide feedback to examiners on their findings and suggest changes in working practice immediately after doing the checks, as part of a "Quality Loop" for continuous improvement.

The results are made anonymous and collected in an electronic database to monitor overall compliance of search and examination work. Quarterly reports of these results are provided to the Principal Director of each Joint Cluster (JC). Overall DG1 results are provided directly to the Quality Board and VP1.

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.*
- (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.*

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

Organisational changes were made which, although independent of the review under PCT/GL/ISPE sections 21.10-21.15, enhance the provision and maintenance of electronic tools and IT to support S&E. They are shown in the organigram.

New "Applications Management" directorates were established in each DG. Applications Management DG1 ensures that the maintenance and development of tools supporting S&E work matches the needs DG1 Operations. Similarly, Applications Management DG2 ensures that electronic tools necessary for DG2 to support DG1 operations are in place.

Provision and maintenance of electronic tools is the responsibility of four new principal directorates in DG2.

- PD IM (Information Management) - Infrastructure, support and facilities enabling IT work.
- PD ITIS (IT Infrastructure and Services) - provision of IT facilities
- PD OEA (Office-wide and External Automation) - provision and maintenance of electronic tools used in all DGs and by parties outside the office
- PD PGA (Patent Granting and Administration) - development and maintenance of electronic tools for S&E

S&E tools development is also assured by dedicated projects. The office introduced the Prince2™ project management method to provide a controlled approach and environment for development projects.

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.*

These capabilities are now monitored and controlled by the PA-OQC methodology (Patent Administration Operational Quality Control) for patent granting administration and formalities in PD Pat. Admin. in DG2. This involves operational checks of administrative work similar in concept to the CL-OQC checks for S&E.

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 introduction of CL-OQC (see 21.03(b) above) allows the office to quantify the extent of compliance of S&E work with PCT/GL/ISPE. A dedicated sampling, checking and reporting procedure provides each JC with quarterly reports on the nature and extent of deficiencies of S&E work performed under the PCT.

(b) Two reviews of the QMS have taken place to date. The first review is that called for under ' 21.10 and ' 21.11 and was submitted to the Quality Board. The second involved a review to assess compliance with ISO 9001:2000 and was performed out by external consultants, who prepared a report for top management.

(c) i)

The CL-OQC procedure specifies action to be taken to correct deficient S&E work for those files selected as part of the random sampling procedure. Quality Nominees report any deficiency found during their checks to the examiner, and suggest corrections. Results show that the examiner corrects the work in the vast majority of cases, with less than 2% of cases being disputed. A mediation procedure ensures that a decision is arrived at regarding release of the work.

(c) ii), (d)

A harmonised approach to ensuring corrective action on the basis of CL-OQC results across all JCs is under development.

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**

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: - **Unchanged**
- (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.

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 was carried out in 2007 (see response to '21.07(b) above). This has identified the actions necessary to ensure that points (a), (b) and (c) are consistently met.

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.*

Joint DG1 / DG2 Quality Board

The office identified the need to work across organisational boundaries when implementing and reviewing a QMS for S&E work. As a result, the joint DG1 / DG2 quality board was established (Ref. 1) to supervise, monitor and support implementation of the QMS. Its mandate includes advising on reviews of the QMS and deciding on responses to the results. The board is made up of three permanent members: The Principal Director (PD) for Quality Management (DG2, Chair); a DG1 PD responsible for Quality Management in DG1, nominated by VP1; and the PD Patent Administration (DG2). The board meets at least once per quarter.

[End of report]