**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 2009**

Date of main report and any supplemental reports to which this is a supplement: 18 December 2006 (21.17 Report)
21 December 2007 (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.* **- Unchanged in 2008**
- 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:

- Extension of CL-OQC methodology (Cluster-level Operational Quality Control) to include cross-site checking between Munich, The Hague and Berlin of DG1 (Operations).
  See response to '21.03(b); '21.07(a), (d) below

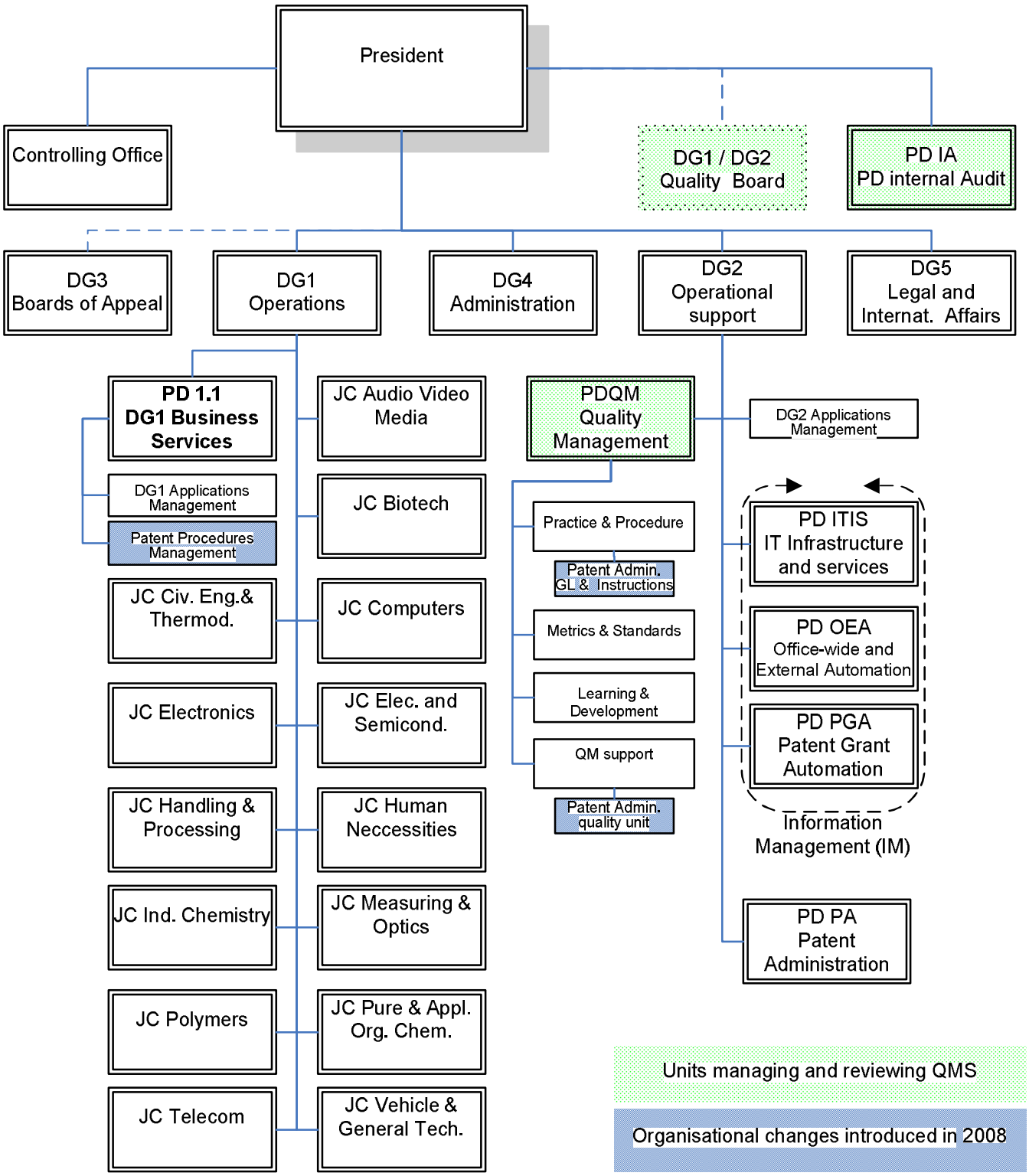
- Continuation of the PA-OQC methodology (Patent Administration Operational Quality Control) for patent granting administration and formalities in the DG2 Principal Directorate (PD) for Patent Administration (PD Pat. Admin.).
  See response to '21.06a), b); '21.07(a) below

- 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.

  - The EPO has centralised the units responsible for developing and implementing a QMS by moving the quality unit in PD Patent Administration to Directorate Quality Management Support in PD Quality Management (DG2).
  - The DG1 Quality Committee is the body dealing with operational quality issues within DG1. The vice president of DG1 has nominated a PD sponsor who is responsible for coordinating all quality issues within DG1. The sponsor PD will receive administrative and operational support from the director responsible for the directorate Patent Procedures Management, whenever appropriate
  - The EPO has also centralised the departments for establishing Guidelines and instructions to administrative staff by moving the unit concerned from PD Patent Administration to its search and examination equivalent, Directorate Patent Practice in PD Quality Management.
  - The EPO intends to centralise its training departments under Principal Directorate Human Resources in DG4 in the course of 2009.

**Organigram January 2009**



## 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 2008** *;*

*(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) was further developed in 2008 including a pilot to test the 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 within the same Joint Cluster (JC) and technical field. If necessary, corrective action will be taken to ensure that work is produced to the same standards at each site. Thus Quality nominees (QN) are now required to check some work in their field done by examiners at other sites.

- Quarterly reporting of CL-OQC results to the Principal Director of each JC was replaced by six-monthly reporting to relieve the administrative workload of producing the reports, which was found to be excessive.

## 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 extension and continuation of the CL-OQC in-process checks in 2008 (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 2008. The results indicate the extent of compliance of the search and examination products produced by the office as a whole.

(b)

- Two reviews of the QMS were performed in 2007. The first review is that called for under '21.10 and '21.11 and was submitted to the Quality Board. The second was a review to assess compliance with ISO 9001:2000 and was performed by external consultants. The state of the EPO's QMS and plans for implementation in the light of these reviews were presented to top management in 2008.

(c) i)

- Unchanged

(c) ii), (d)

- A total of 13841 applications were checked under CL-OQC during 2008, 4312 of these filed under the PCT.

- A harmonised approach to 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).

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

- A survey of the system for internally classifying patent documents was carried out. The classification process supports search work and the survey identified areas for action in different technical fields. The objective is to improve the effectiveness of classification work where necessary, and to identify areas where additional search tools could bring benefits.

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 have been prepared and are in the process of being presented to all operational management teams. Plans have been prepared to cascade these presentations 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:* **- 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.*

- User Satisfaction Surveys were carried out in 2008 on the search and examination work of ten of the fourteen Joint Clusters.

- Results were presented to the management teams of eight of these Joint Clusters in 2008. Results for the other two will be presented in 2009. The surveys of the remaining four Joint Clusters will be undertaken in 2009.

## 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).

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 2008. It decided on how best to exploit and communicate CL-OQC results (including the formatting and content of reports to DG1on quality of S&E work) and the launching of cross-site CL-OQC, whereby work produced on one site is checked by peers on one of the other sites.

- 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 and will monitor their implementation in 2009.

[End of report]