

PATENT COOPERATION TREATY (PCT)

Common Quality Framework for International Search and Preliminary Examination

SUPPLEMENTAL REPORT ON QUALITY MANAGEMENT SYSTEMS

prepared by **EUROPEAN PATENT OFFICE**

This supplemental report relates to the quality management system established by this Office as set forth in our report under PCT/GL/ISPE section 21.29 on 12 October 2010.

As a result of our most recent internal review under the International Search and Preliminary Examination Guidelines paragraphs 21.25-21.28, this Authority has made modifications to its QMS as discussed below.

The modifications are given with reference to the sections of the revised template for responses to PCT/GL/ISPE Chapter 21.29 to which the changes relate.

The Authority should describe any changes made to its QMS making reference to the specific sections of the previous main report, and/or making reference to any supplemental report(s) under paragraph 21.30 compiled in accordance with this template.

If no changes have been made to its QMS since the last report, the Authority should indicate such.

INTRODUCTION (PARAGRAPHS 21.01 TO 21.03)

- no changes

Current activities are:

- The project to achieve ISO9001:2008 compliance in core processes of the EPO has reached its halfway point. A draft Quality Manual covering some key processes has been launched and is being evaluated.
- Following CL-OQC and PA-OQC a pilot study was started on Operational Quality Control of Classification (Class-OQC). The results of the pilot were evaluated and incorporated in

an extended test covering about 15% of the IPC . The test ends in 4Q 2011, full rollout to all fields is planned for 2012.

- An "IT roadmap" was prepared as a follow-on to SPP focusing on improvement of core processes and the IT environment. One goal amongst others is to increase the efficiency by re-engineering processes.

1. LEADERSHIP AND POLICY (PARAGRAPHS 21.04 TO 21.09)

21.04 *Confirm that the following are clearly documented, and that this documentation is available internally:*

(a) *The quality policy established by top management.*

- An updated policy reflecting the offices new mission has been adopted internally.

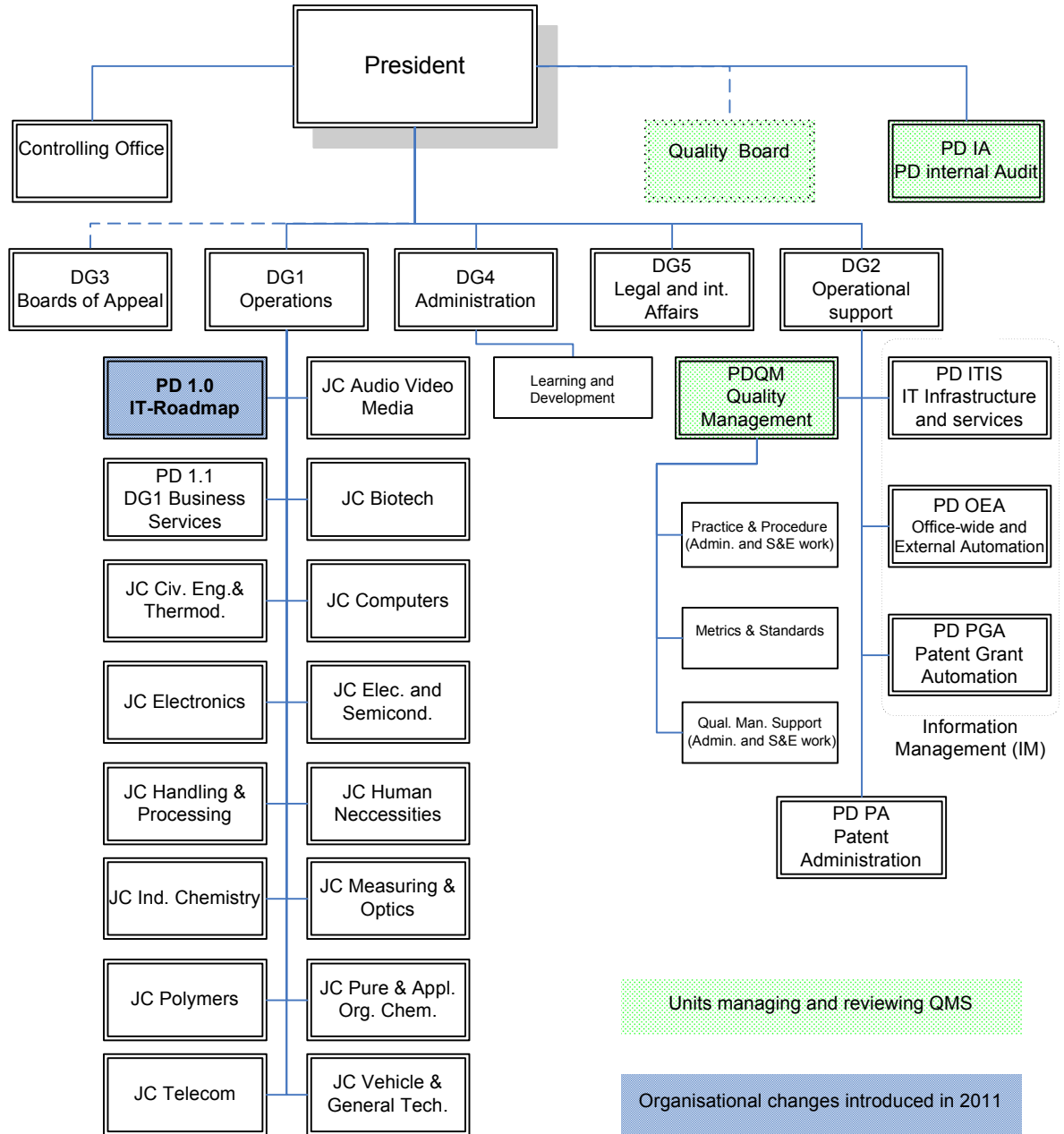
(b) *The roles and names of those bodies and individuals responsible for the QMS, as delegated by top management.*

- no changes

(c) *An organizational chart showing all those bodies and individuals responsible for the QMS.*

- See organigram and comments below.
 - DG1 Operations created a new Principal Directorate 1.0. responsible for the execution of the IT Roadmap.

Organigram November 2011



21.05 *Indicate (e.g. by means of a table as shown below) the extent of compatibility between the Authority's QMS and the requirements of Chapter 21 of these International Search and Preliminary Examination Guidelines. Alternatively, indicate where the Authority is not yet compliant with these requirements.*

- no changes

21.06 *Indicate with reference to the organizational chart those bodies and mechanisms management uses to ensure:*
(a) *the effectiveness of the QMS; and*

- no changes

(b) *that the process of continual improvement progresses.*

- The DG1/ DG2 Quality Board has been expanded with a member of DG5 (legal affairs)

21.07 *Indicate how management of the Authority communicates to its staff the importance of meeting treaty and regulatory requirements including:*
(a) *those of this standard; and*

- no changes

(b) *complying with the Authority's QMS.*

- no changes

21.08 *Indicate how and when top management of the Authority or delegated officers:*
(a) *conducts management reviews and ensures the availability of appropriate resources;*
(b) *reviews quality objectives; and*
(c) *ensures that the quality objectives are communicated and understood throughout the respective Authority.*

- (a) and (c): The President has instigated the development of a "Quality Roadmap" that sets out the activities the EPO will undertake to enhance quality. The Office is committed to achieving compliance with the ISO9001 standard by the end of 2012 and certification to the standard in the course of 2013.

- (b): no change

21.09 *Indicate whether top management or delegated officers of the Authority perform an internal review of the QMS in accordance with paragraphs 21.25-21.28:*

(a) *at least once per year (cf. paragraph 21.25);*

- The Principal Director of PDQM met with top management to inform about quality achievements in 2010 against objectives set, and the latest developments regarding quality matters. The next formal review meeting is planned for 2012.

(b) *in accordance with the minimum scope of such reviews as set out in Section 8, namely:*

(i) *to determine the extent to which the QMS is based on Chapter 21 (cf. paragraphs 21.25, 21.27(a));*

- This is done in form of this report. The EPO achieved compliance with the requirements for the Record of Search in July 2010.
 - (ii) *to determine the extent to which Search and Examination work complies with PCT Guidelines (cf. paragraphs 21.25, 21.27(a));*
- no changes
 - (c) *in an objective and transparent way (cf. paragraph 21.25);*
- no changes
 - (d) *using input including information according to paragraphs 21.27 (b)-(f);*
- no changes
 - (e) *recording the results (cf. paragraph 21.28).*
- no changes

2. RESOURCES (PARAGRAPHS 21.10 TO 21.14)

- 21.10 *Explanatory note: The granting of ISEA status means that the Authority has demonstrated it has the infrastructure and resources to support the search and examination process. Chapter 21 calls for assurance that the Authority can continually support this process while accommodating changes in workload and meeting QMS requirements. The responses to Sections 21.11 to 21.14, below, should provide this assurance.*
- 21.11 *Human resources:*
- (a) *Provide information about the infrastructure in place to ensure that a quantity of staff:*
 - (i) *sufficient to deal with the inflow of work;*
 - no changes
 - (ii) *which maintains the technical qualifications to search and examine in the required technical fields; and*
 - no changes
 - (iii) *which maintains the language facilities to understand at least those languages in which the minimum documentation referred to in Rule 34 is written or is translated is maintained and adapted to changes in workload.*
 - no changes
 - (b) *Describe the infrastructure in place to ensure that a quantity of appropriately trained/skilled administrative staff is maintained and adapted to changes in workload:*
 - (i) *at a level to support the technically qualified staff and facilitate the search and examination process;*
 - (ii) *for the documentation of records.*

- no changes

21.12 *Material resources:*

(a) *Describe the infrastructure in place to ensure that*

- (i) *appropriate equipment and facilities such as IT hardware and software to support the search and examination process are provided and maintained;*

- no changes

- (ii) *at least the minimum documentation referred to in Rule 34 is available, accessible, properly arranged and maintained for search and examination purposes. State whether it is on paper, in microform or stored on electronic media, and where.*

- no changes

(b) *Describe how instructions*

- (i) *to help staff understand and adhere to the quality criteria and standards, and*
- (ii) *to follow work procedures accurately and consistently are documented, provided to staff, kept up-to-date and adapted when necessary.*

- (i) - (ii) no changes

21.13 *Training resources:*

Describe the training and development infrastructure and program which ensures that all staff involved in the search and examination process:

- (i) *acquire and maintain the necessary experience and skills; and*
- (ii) *are fully aware of the importance of complying with the quality criteria and standards.*

- no changes

21.14 *Oversight over resources:*

Describe the system in place for continuously monitoring and identifying the resources required:

- (a) *to deal with demand; and*
- (b) *comply with the quality standards for search and examination.*

- no changes

3. MANAGEMENT OF ADMINISTRATIVE WORKLOAD (PARAGRAPH 21.15)

21.15 *Indicate how the following practices and procedures for handling search and examination requests and performing related functions such as data-entry and classification are implemented:*

- (a) *Effective control mechanisms regarding timely issue of search and examination reports to a quality standard as set by the respective Authority; and*

- no changes

(b) *Appropriate control mechanisms regarding fluctuations in demand and backlog management.*

- no changes

4. QUALITY ASSURANCE (PARAGRAPH 21.16)

21.16 *The following are required quality assurance measures for timely issue of search and examination reports of a quality standard in accordance with the Guidelines. Indicate how the following are implemented:*

(a) *An internal quality assurance system for self assessment, involving verification, validation and monitoring of searches and examination work:*

(i) *for compliance with these Search and Examination Guidelines;*

- CL-OQC (Cluster-level Operational Quality Control) now includes checking of work across the three sites of DG1 Operations (Munich, The Hague, Berlin) to identify site-related differences in practice and to harmonize working procedures. Corrective action is taken - where necessary - to ensure that work is produced to the same standards at each site. Around 1% of total production is checked across sites and 5% on-site. A dedicated CL-OQC 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. A total of 13537 applications were checked under CL-OQC during 2010, 2069 of these were checked across sites and 4788 of these filed under the PCT.
- A harmonized 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 assisted by L&D. Field- specific training on amendments filed (Article 123 (2) EPC) and clarity objections and added subject-matter (See 21.17 below) was continued in 2010.
- Presentations of CL-OQC results for 2010 were made to all operational management teams. These presentations were cascaded to all examination staff in 1st half of 2011.
- Extension of the PA-OQC methodology (Patent Administration Operational Quality Control) for patent search and granting administration and formalities in the DG2 Principal Directorate Patent Administration (PD Pat. Admin.) by checking the process of PCT search non-unity cases and the formalities procedures at the Receiving Office acting on behalf of WIPO. As from 2011 all checks are performed as cross-unit checks to avoid conflicts of interest and immediate feedback on necessary corrective actions can be forwarded to the responsible operational level.
- A project to develop classification operational quality control (Class-OQC) based on the CL-OQC methodology completed the "extended test" stage in 2011. An experienced classifier responsible for classification practice in a given field acts as "quality nominee" for that field, checking the classification of a sample of the search files and incoming newly-published documents classified there. The aim is to monitor non-compliances, perform correction and initiate corrective action when necessary. A key part of the project is to document classification practice in each field in a consistent way: the documentation produced for this will also be used in bilateral classification co-operation with the USPTO (CPC). Training is in progress for Class-OQC to be rolled out to all technical fields in 2012.

(ii) *for channeling feedback to staff.*

- no change

5. COMMUNICATION (PARAGRAPHS 21.17 TO 21.19)

21.17 *Inter-Authority communication:*

Provide the name, job title and contact details of the Authorities designated quality contact person who will take responsibility for:

- helping identify and disseminate best practice among Authorities;*
- fostering continual improvement; and*
- providing for effective communication with other Authorities to allow for prompt feedback from them so that potential systemic issues can be evaluated and addressed.*

- no change

21.18 *Communication and guidance to users:*

Describe the system in place for monitoring and using customer feedback including at least the following elements:

- An appropriate system for*
 - handling complaints and making corrections;*

- no change

(ii) *taking corrective and/or preventative action where appropriate; and*

- no change

(iii) *offering feedback to users.*

- no change

- A procedure for:*
 - monitoring user satisfaction and perception; and*
 - for ensuring their legitimate needs and expectations are met.*

- User Satisfaction Surveys were carried out between 2010 and 2011 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 2011.

(c) *Clear, concise and comprehensive guidance and information to users (particularly unrepresented applicants) on the search and examination process, giving details of where it is to be found e.g. link to Authority's web site, guidance literature.*

- Given in Guidelines for filing applications and the Guide for applicants, available via the office web site under "Applying for a patent" → "Guide for applicants".

(d) *An indication of where and how the Authority makes its quality objectives publicly available for the users.*

- no change

21.19 *Communication with WIPO and designated and elected Offices:*
Describe how the Authority provides for effective communication with WIPO and designated and elected offices. In particular describe how the Authority ensures that WIPO feedback is promptly evaluated and addressed

- no change

6. DOCUMENTATION (PARAGRAPHS 21.20 TO 21.23)

21.20 *Explanatory note: The QMS of the Authority needs to be clearly described and implemented so that all processes in the Authority and the resulting products and services can be monitored, controlled, and checked for conformity. This is done in the documents that make up the Quality Manual of the Authority (see paragraph 21.21). (Note: This point is informative. No response is required by the template to paragraph 21.20)*

21.21 *The documents that make up the Quality Manual serve to document the procedures and processes affecting the quality of work, such as classification, search, examination and related administrative work. In particular, the Quality Manual indicates where to find instructions on the procedures to be followed.*

For the purposes of this report indicate:

(a) *the documents making up a Quality Manual that have been prepared and distributed;*

- no change

(b) *the media on which it is supported (e.g. Internal Publication, Internet, Intranet); and*

- no change

(c) *document control measures taken e.g. version numbering, access to latest version.*

- no change

21.22 *Indicate whether the documents making up the Quality Manual include the following:*

(a) *the quality policy of the Authority including a clear statement of commitment to the QMS from top management;*

(b) *the scope of the QMS, including details of and justification for any exclusions;*

(c) *the organizational structure of the Authority and the responsibilities of each of its departments;*

(d) *the documented processes carried out in the Authority such as receipt of incoming applications, classification, distribution, search, examination, publication and support processes, and procedures established for the QMS, or references to them;*

(e) *the resources available for carrying out the processes and implementing the procedures; and*

(f) *a description of the interaction between the processes and the procedures of the QMS.*

- no changes

21.23 Indicate which types of records the Authority maintains, such as:

- (a) *a definition of which documents are kept and where they are kept;*
- (b) *results of management review;*

- no changes

- (c) *training, skills and experience of personnel;*

- no changes

- (d) *evidence of conformity of processes, resulting products and services in terms of quality standards;*

- no changes

- (e) *results of reviews of requirements relating to products;*

- (f) *the search and examination processes carried out on each application;*

- no changes

- (g) *data allowing individual work to be tracked and traced;*

- no changes

- (h) *records of QMS audits;*

- no changes

- (i) *actions taken re. non-conforming products, e.g. examples of corrections;*

- no changes

- (j) *actions taken re. corrective action;*

- no changes

- (k) *actions taken re. preventative action; and*

- no changes

(l) *search process documentation as set out in Section 7.*

7. SEARCH PROCESS DOCUMENTATION (PARAGRAPH 21.24)

21.24 *For internal purposes the Authority should document its search process. The Authority should indicate*

- (a) *which of the following are included in this record:*
 - (i) *the databases consulted (patent and non patent literature);*
 - (ii) *the keywords, combinations of words and truncations used;*
 - (iii) *the language(s) in which the search was carried out;*
 - (iv) *the classes and class combinations searched, at least according to the IPC or equivalent;*
 - (v) *a listing of all search statements used in the databases consulted.*

(b) *which other information relevant to the search itself is included in this record e.g. a statement of the subject of search; details of special relevance to internet searching; a record of documents viewed; on-line thesaurus, synonym or concept databases, etc.*

(Explanatory note: The IA is requested to list other information it may collect to monitor and improve the search process)

(c) *which special cases are documented and whether records are kept denoting any:*
(i) *limitation of search and its justification*
(ii) *lack of clarity of the claims; and*
(iii) *lack of unity.*

- (a)-(c) The compliance with the implemented internal instructions (PPN 4/10) for recording searches in the EPO search record (the "Compte Rendu de Recherche" or CRdR) is now systematically monitored by the CL-OQC process.

8. INTERNAL REVIEW (PARAGRAPHS 21.25 TO 21.28)

21.25 *Explanatory note: The Authority should report on its own internal review arrangements. These reviews determine the extent to which it has established a QMS based on the model of Chapter 21 and the extent to which it is complying with the QMS requirements and the Search and Examination Guidelines. The reviews should be objective and transparent to demonstrate whether or not those requirements and guidelines are being applied consistently and effectively and should be undertaken at least once a year. With reference to point 21.08 of this template, the Authority may provide additional information on its internal review arrangements under this section if it so wishes.*

- The EPO's quality policy is currently under revision.
- A dashboard presenting process and product quality indicators to managers is in place, and is being further developed.

21.26-

21.28 *These arrangements are reported according to this template in Section 1, above, at points 21.04 - 21.09. The Authority may provide additional information on further inputs to its internal reviews under this section, if it so wishes*

- The DG1/DG2 Quality Board met four times in each of 2010 and 2011. A critical review of results generated by PA-OQC, CL-OQC, the User Satisfaction Survey (USS) and the complaints received by the office took place and fields of improvement were identified.
- Timeliness data of search and examination of PCT Ch. I and II work are monitored closely.

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