

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)

The quality of the products and services delivered by the EPO is recognised across the patent world and EPO management is committed to maintain and even enhance the Office's leading position. This Office aims to achieve this by sustaining a strong and effective commitment to quality at all levels. By 2014, the Office will have completed the implementation project of a new Quality Management System for the patent-grant process.

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.*

The EPO is dedicated to meet or exceed its stakeholders' needs and expectations and to remain global quality leader of patent products and services. The performance and reliability of the EPO are based on the professional competence and personal responsibility of its management and staff.

The management and staff commit themselves to the following principles:

- Legal certainty - The users of the European patent system expect that patents granted by the EPO have the highest presumption of legal validity. The EPO therefore grants patents and provides decisions fully consistent with the applicable legal framework, in particular the requirements of the EPC and other international treaties in both an efficient and timely manner.
- Service - The EPO provides reliable, efficient and effective services for the benefit and satisfaction of all users of the European patent system and the European society.
- Continual improvement - The EPO commits itself to continually improving its training, tools, procedures and processes for enhancing the thoroughness, consistency, and timeliness of its products and services and the skills and competences of its staff.
- Involvement - The EPO has a culture that encourages and empowers management and staff to participate in quality improvement activities.
- Informed decision making - Decisions taken at the EPO are based on facts enabling to review, challenge and adapt planned actions as well as to improve the products and services delivered by the EPO.
- Openness - The EPO engages with its users to enhance the quality and effectiveness of its processes and services.
- Commitment - The top management of the EPO is committed to this Quality Policy through active participation in quality improvement activities and leadership by example.

In pursuing the above-mentioned principles the EPO builds on the culture of quality and excellence that has established its reputation.

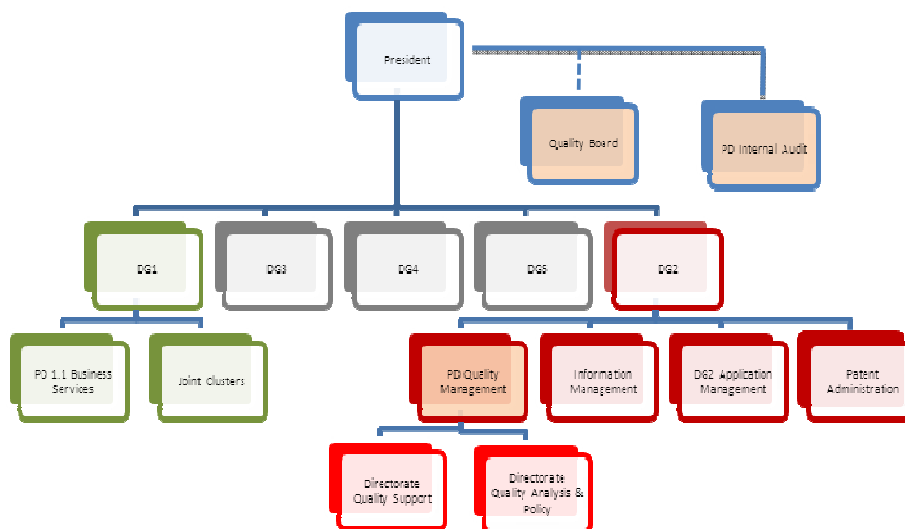
(b) *The roles and names of those bodies and individuals responsible for the QMS, as delegated by top management.*

- President: The President has the overall responsibility for the QMS. He establishes the Quality Policy and quality objectives to support the QMS.
- The Management Representative for Quality: The Management Representative for Quality coordinates the implementation, maintenance and improvement of the QMS at all levels of the organization. This role is assigned to the Vice-President of Directorate General 2.
- Quality Board: The Quality Board ensures the integration of the Quality Management System into the Office's management system. It has the function to evaluate the effectiveness the Quality Management System and support it by recommending and monitoring the implementation of improvement measures.
- Principal Directorate Quality Management: This Principal Directorate has a centralised oversight of all quality aspects. It is dedicated to the design, implementation and maintenance of a Quality Management System for the patent-grant process. The activities and responsibilities of this Principal Directorate aim to suit the needs of internal and external stakeholders under the framework of the Quality Management System for

the patent-grant process. It also works closely with Operations by supporting, informing and guiding in quality principles.

As of July 2013, Principal Directorate Quality Management includes two Directorates: Directorate Quality Analysis & Policy (responsible for facilitating the policy making process by providing information, data, metrics analysis and recommendations to management) and Directorate Quality Support (responsible for managing the Quality Management System by the development and maintenance of quality services).

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



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 results of quality controls serve - together with other feedbacks - as a basis for identifying corrective and preventive actions (e.g. providing specific training for staff, implementing suitable changes in practice and procedures, etc.). The implementation and the effectiveness of these actions are monitored by operational departments as well as by the Quality Board. A Quality Management Review is carried out every year in order to assess the efficiency and effectiveness of the Quality Management System.

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*

- Activities reports (by top management and Principal Directorate Quality Management) emphasize the importance of quality. Furthermore, quality data in the form of "Quality Reports" are presented to all Operational management teams, and are communicated to staff.

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

- Internal communiqués by top management regarding the Quality Management System implementation, the yearly quality objectives and results achieved in the previous year. Further communication means are used to address quality matters to all levels of the organization (e.g. intranet quality site, posters, flyers, workshops, events)

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) to (c) As part of the "Quality Roadmap", the Quality Board has been strengthened by the appointment of VP2 (Mr A. Casado) to chair the Board. The first outcome of this enhanced Quality Board was the provision of a set of quality objectives for top level customer satisfaction, process and product quality which have been endorsed by the President. In the future, these quality objectives will be produced at the beginning of each year. They will enable the top management to evaluate whether work is proceeding as planned and the desired results are being produced.

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);*

- A yearly evaluation of the Quality Management System is presented to the top management by the Quality Board.

(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));*

- no changes

(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).*
- Quality data are presented to all Operational management teams, and are communicated to staff.

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;*

- Since 2012 the Quality Board proposes quality objectives according to the strategy for quality, which objectives are endorsed by top management.
- Quality-related results are presented to operational management teams using integrated quality reports. These reports focus on key quality issues and present the most relevant quality aspects which can be derived from different quality-related data sources, e.g. user satisfaction surveys, operational quality control, quality indicators, complaints.
- Identification of the key quality issues allow development of corrective, preventive and/or improvement actions, which efficiency is then monitored.
- In early 2014, CL-OQC (Cluster-level Operational Quality Control) will be discontinued and replaced by a new approach for conformity assurance in search and examination). This procedure will be applied to sampled applications; it keeps a record of any nonconformity detected and of the re-verification step before the product is released.
- The methodology for performing operational quality control in the area of patent administration and formal procedures related to search and examination (PA-OQC, "Patent Administration Operational Quality Control") is being adapted and optimized to better suit business needs in Principal Directorate Patent Administration. The new methodology started in 2013 and is now being tested internally in several operational units of Principal Directorate Patent Administration. The new methodology is scheduled to go live in the beginning of 2014.
- The first results from Classification operational quality control (Class-OQC) which were based on the sample of documents checked in 2013 have been reported to Management in the framework of integrated quality reports. In the context of bilateral quality assurance for CPC, classification Quality Nominees in the EPO are providing their partners in the USPTO with detailed feedback on a sample of the documents they classify. The first data from statistical comparison of patent families independently classified with CPC symbols by both offices were obtained in Q3 2013.

(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:

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

- Directorate Quality Support (Principal Directorate Quality Management). The current Director is Nigel Berrington, who can be contacted via the email address dqs@epo.org.
- Directorate Quality Analysis and Policy (Principal Directorate Quality Management). The current director is Jörg Machek, who can be contacted via the email address dqa@epo.org.

21.18 *Communication and guidance to users:*

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

(a) *An appropriate system for*

(i) *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

(b) *A procedure for:*

(i) *monitoring user satisfaction and perception; and*

(ii) *for ensuring their legitimate needs and expectations are met.*

- Directorate Quality Support is responsible for the administration and management of external complaints submitted at the EPO. Depending on the nature of the complaint, other departments may be involved in the complaint handling procedure (e.g. for providing feedback and (if required) for taking suitable corrective and/or preventive actions).
- In 2013, the complaint handling procedure has been reviewed and streamlined under the lead of this directorate with the aim to set up a procedure which (i) ensures that all complaints filed at the Office are registered and treated in a harmonized manner, meeting the complainant's legitimate expectations of a complete, reasoned and timely reply; (ii) enables identifying recurrent causes for complaint, and (iii) ensures that issues underlying complaints are suitably addressed by taking appropriate corrective and/or preventive measures.
- Starting from 01.01.2014, the EPO web site will also include a web form for enabling the submission of complaints online.

(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.*

- no changes

(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.*

- no changes

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.*

- no changes

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*

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