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WORLD INTELLECTUAL PROPERTY ORGANIZATION
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**INTERNATIONAL PATENT COOPERATION UNION
(PCT UNION)**

MEETING OF INTERNATIONAL AUTHORITIES UNDER THE PATENT COOPERATION TREATY (PCT)

Sixteenth Session
Seoul, March 16 to 18, 2009

QUALITY FRAMEWORK:
PROPOSAL FOR REVISION OF THE PCT INTERNATIONAL SEARCH AND PRELIMINARY EXAMINATION GUIDELINES

Proposal by the European Patent Office

BACKGROUND

1. As set out in the report of the Thirteenth Session of the Meeting of International Authorities (MIA) held in Geneva in May 2006 (document PCT/MIA/13/8), the MIA agreed that further work on a quality framework should be undertaken, led by the European Patent Office (EPO). The Meeting agreed that modifications of Chapter 21 of the PCT International Search and Preliminary Examination Guidelines (PCT Guidelines) should be considered.

2. During the MIA held in Geneva in February 2007, the EPO noted that its involvement in the European Patent Network had prevented it from making much progress on this matter, and suggested that further work by the Meeting on the PCT quality framework, which the Office was prepared to continue to lead, should await progress in the European context.

3. The MIA agreed (document PCT/MIA/14/8) and invited the EPO to report on such developments to the next session of the Meeting.

4. The Annex to this document contains the EPO's proposal for a revised text of PCT Guidelines Chapter 21.

BASIC ASSUMPTIONS FOR THE FUTURE DEVELOPMENT OF CHAPTER 21 OF THE GUIDELINES

5. Chapter 21 of the PCT Guidelines will continue to describe a minimum set of requirements that each Authority should use as a *model* for establishing their individual quality scheme.

6. Each Authority has the freedom to establish its own QMS. It should be compliant with Chapter 21 of the PCT Guidelines.

7. The Meeting is invited to comment on the basic assumptions and proposed revised text contained in this document.

[Annex follows]

ANNEX

DRAFT REVISED TEXT OF CHAPTER 21 OF
THE PCT INTERNATIONAL SEARCH AND
PRELIMINARY EXAMINATION GUIDELINES

Drafted by the European Patent Office,
Directorate Quality Management Support

14 January 2009

PART VII
QUALITY

Chapter 21
A Common Quality Framework for International Search and Preliminary Examination

Introduction

21.01 International Searching Authorities and International Preliminary Examining Authorities are entrusted to apply and observe all the common rules of international search and examination. Although applicants can generally expect the International Searching and Examining Authorities to act in accordance with the Guidelines, due to the involvement of several States in the international search and examination process and to the multitude of personnel within the various Authorities, some variability is inherent to the international search and examination process. At the same time, it is recognized that minimizing inconsistencies between or within the International Searching and Examining Authorities is crucial to the unqualified acceptance of an Authority's work product by the States.

21.02 This chapter sets out the main features of a quality framework for international search and preliminary examination. It describes a minimum set of criteria that each International Authority ("Authority") should use as a model for establishing their individual quality scheme.

21.03 Each Authority should establish and maintain a quality management system (QMS) which complies with the following requirements with regard to:

1. Leadership and policy
2. Resources
3. Management of administrative workload
4. Quality assurance
5. Communication
6. Documentation
7. Search process documentation

Additional Provisions:

8. Internal review
9. Reporting arrangements

1. Leadership and policy

21.04 Top management of the Authority is responsible for the development and implementation of a Quality Management System (QMS). Top management should establish a quality policy for the Authority and it should delegate responsibilities for the QMS and document these in an organisational chart.

21.05 Management should ensure compatibility of its QMS with the requirements of these International Search and Preliminary Examination Guidelines.

21.06 Management should ensure the effectiveness of the QMS and that the process of continual improvement progresses.

21.07 Management of the Authority should communicate to its staff the importance of meeting treaty and regulatory requirements including those of this standard and complying with the Authority's QMS.

21.08 Top management of the Authority or delegated officers should conduct management reviews and ensure the availability of appropriate resources. It should regularly review quality objectives and ensure that they are communicated and understood throughout the respective Authority.

21.09 Top management or delegated officers of each Authority will review its respective QMS at regular intervals. The minimum scope of such reviews and the frequency is set out in Section 8.

2. Resources

21.10 An Authority should be able to accommodate changes in workload and should have an appropriate infrastructure to support the search and examination process and comply with the QMS requirements and these Search and Examination Guidelines.

21.11 Each Authority should have sufficient human resources:

- A quantity of staff sufficient to deal with the inflow of work and which maintains the technical qualifications to search and examine in the required technical fields and the language facilities to understand at least those languages in which the minimum documentation referred to in Rule 34 is written or is translated;

- Appropriately trained/skilled administrative staff at a level to support the technically qualified staff and facilitate the search and examination process, and for the documentation of records;

21.12 Each Authority should have sufficient material resources:

- Appropriate equipment and facilities, such as IT hardware and software, to support the search and examination process;

- Possession of, or access to, at least the minimum documentation referred to in Rule 34, properly arranged for search and examination purposes, on paper, in microform or stored on electronic media;

– Comprehensive and up-to-date instructions to help staff understand and adhere to the quality criteria and standards and follow work procedures accurately and consistently;

21.13 Each Authority should have sufficient training resources:

– An effective training and development program for all staff involved in the search and examination process to ensure they acquire and maintain the necessary experience and skills and are fully aware of the importance of complying with the quality criteria and standards; and

21.14 Each Authority should have oversight over its resources:

– A system for continuously monitoring and identifying the resources required to deal with demand and comply with the quality standards for search and examination.

3. Management of administrative workload

21.15 The Authority should have in place the following minimum practices and procedures for handling search and examination requests and performing related functions such as data-entry and classification:

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

– Appropriate control mechanisms regarding fluctuations in demand and backlog management.

4. Quality assurance

21.16 An Authority should have procedures regarding timely issue of search and examination reports of a quality standard in accordance with these Search and Examination Guidelines. Such procedures should include:

– An effective internal quality assurance system for self assessment, involving verification and validation and monitoring of searches and examination work for compliance with these Search and Examination Guidelines and channelling feedback to staff;

– An effective system of measurement and collection of data and reporting, and commitment to using it to ensure the continuous improvement of the established processes,

– A system for verifying the effectiveness of actions taken to address deficiencies and to prevent issues from recurring.

5. Communication

21.17 *Inter-Authority communication*

- To help identify and disseminate best practice among Authorities and foster continual improvement, each Authority should provide for effective communication with other Authorities to allow for prompt feedback from them so that potential systemic issues can be evaluated and addressed.

- The Authority should nominate and make known to other Authorities the name of a quality contact person.

21.18 *Communication and guidance to users*

The Authority should have in place a system for monitoring and using customer feedback including at least the following elements:

- An appropriate system for handling complaints and making corrections, and taking corrective and/or preventative action where appropriate and offering feedback to users.

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

- Clear, concise and comprehensive guidance and information to users (particularly unrepresented applicants) on the search and examination process which could be included on each Authority's web site as well as in guidance literature.

- The Authority should make its goals in terms of quality publicly available for the users.

21.19 *Communication with WIPO and designated and elected Offices*

To help improve performance and foster continual improvement, each Authority should provide for effective communication with WIPO and designated and elected Offices to allow for prompt feedback from them so that potential systemic issues can be evaluated and addressed.

6. Documentation

21.20 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.

21.21 Therefore the Authority should provide a reference for its staff and management in the form of a Quality Manual, which documents all the procedures and processes affecting the quality of work, such as classification, search, examination and related administrative work. In the manual it is to be indicated where instructions on the procedures to be followed may be found.

21.22 The following list indicates the items which are considered to be the type of content of a Quality Manual:

- the quality policy of the Authority including a clear statement of commitment to the QMS from top management;
- The scope of the QMS, including details of and justification for any exclusions;
- The organisational structure of the Authority and the responsibilities of each of its departments;
- 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;
- The resources available for carrying out the processes and implementing the procedures; and
- A description of the interaction between the processes and the procedures of the QMS.

21.23 The following list indicates the types of records that each Authority should maintain:

- A definition of which documents are kept and where they are kept
- Results of management review;
- Training, skills and experience of personnel;
- Evidence of conformity of processes, resulting products and services in terms of quality standards;
- Results of reviews of requirements relating to products;
- The search and examination processes carried out on each application;
- Data allowing individual work to be tracked and traced;
- Records of QMS audits;
- Actions taken re. non-conforming product, e.g. examples of corrections;
- Actions taken re. corrective action;
- Actions taken re. preventative action; and
- Search process documentation as set out in Section 7.

7. Search process documentation

21.24 For internal purposes the Authority should document its search process which may include *inter alia*:

- The databases consulted (patent and non patent literature);
- The keywords, combinations of words and truncations used;
- The language(s) in which the search was carried out;
- The classes and class combinations searched, at least according to the IPC or equivalent; and
- A listing of all search statements used in the databases consulted.
- Each Authority should further document at least for internal purposes special cases such as:
  - Limitation of search and its justification;
  - Lack of clarity of the claims; and
  - Lack of unity.

8. Internal review

21.25 In addition to establishing a quality assurance system for checking and ensuring compliance with the requirements set out in its QMS, 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 and the extent to which it is complying with the QMS requirements and these Search and Examination Guidelines. The reviews should be objective and transparent so as to demonstrate whether or not those requirements and guidelines are being applied consistently and effectively and should be undertaken at least once a year.

21.26 It is open to each Authority to set up its own arrangements but the following is proposed as a guide to the basic components of an internal review mechanism and reporting system.

21.27 The input to each review should include information on:

(a) Conformity with the QMS requirements and these Search and Examination Guidelines;

(b) Any corrective and preventative action taken to eliminate the cause of non-compliance;

(c) Any follow-up action from previous reviews;

(d) The effectiveness of the QMS itself and its processes;

(e) Feedback from customers, including designated and elected Offices as well as applicants; and

(f) Recommendations for improvement.

21.28 Suitable arrangements should be established for monitoring, recording and measuring compliance with the QMS requirements and these Search and Examination Guidelines.

9. Arrangements for Authorities to Report to the MIA

There are two stages in the reporting arrangements.

21.29 *Initial reports*

Each Authority shall submit an initial report to the Meeting of International Authorities under the PCT (MIA) describing what it has done to implement a QMS based on the broad requirements set out in the present document. This would help identify and disseminate best practice among Authorities. MIA should then submit a general initial report on progress to the PCT Assembly.

21.30 *Annual reports*

Following the initial reporting in stage 1, annual reports shall be prepared by each Authority, identifying the lessons learned and actions taken and making recommendations in light of the review.

[End of Annex and of document]