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QUALITY MANAGEMENT SYSTEMS FOR THE PCT INTERNATIONAL AUTHORITIES

Document prepared by the International Bureau

RECENT DEVELOPMENTS

1. The International Searching and Preliminary Examining Authorities under the PCT ("International Authorities") continue to develop, document and discuss their quality management systems. All of the active International Authorities, as well as some of those appointed but not yet operational, again submitted reports on the state of their existing quality management systems. These reports were assessed by the Quality Subgroup which had been set up by the 17th session of the Meeting of International Authorities in 2009 with a view to making recommendations in respect of effective processes and solutions for quality assurance as well as effective quality improvement measures.

2. Annex I to this document contains the report of the Quality Subgroup to the 18th session of the Meeting of International Authorities. Annex II to this document contains the report of the discussions of the Meeting of International Authorities on this subject. As stated in that report, the Meeting emphasized that the Quality Subgroup, in addition to addressing the procedural aspects of quality management which had been the main focus of the Group's discussions so far, should now move to also address the question of effective quality improvement measures, notably the development of quality metrics.

3. The reports from each International Authority are publicly available on the PCT website at *www.wipo.int/pct/en/quality/authorities.html*.

4. The Assembly of the PCT Union is invited to note the contents of this document.

[Annex I follows]

REPORT BY THE QUALITY SUBGROUP TO THE MEETING OF INTERNATIONAL AUTHORITIES UNDER THE PCT

(reproduced from the Annex to document PCT/MIA/18/2)

General Review of Activities

1. The quality subgroup was created by the 17th session of the Meeting of International Authorities and was envisaged as a virtual group, conducting its discussions using an electronic forum. This forum was set up in June 2010, but was little used to begin with.

2. The Swedish Patent and Registration Office invited subgroup representatives to a physical meeting December 2 to 3, 2010 in Stockholm. This was attended by representatives of eight International Authorities (others had been due to arrive but were prevented by airport closures across Europe). Participants felt that this meeting was extremely useful. It improved understanding of the issues and between the representatives, allowing effective work through the electronic forum to begin.

3. The subgroup has completed a first review of quality reports as described below, but has not yet completed its work on identifying effective processes and solutions for quality assurance and effective quality improvement measures.

4. The subgroup recommends to the Meeting of International Authorities that its mandate should be continued with the request to report to the 19th session of the Meeting of International Authorities on the same subjects, that is:

(i) effective processes and solutions for quality assurance; and

(ii) effective quality improvement measures,

taking into account any new information presented to the subgroup in the meantime, including the updating of International Authorities' reports on quality management systems in the second half of 2011 and any further issues raised by the Meeting or by individual International Authorities.

Review of Quality Reports

5. The reports submitted show that the International Authorities concerned are broadly in compliance with the quality framework and work is under way to meet the minor issues of non-compliance which have been identified.

6. The reports were made in accordance with the draft revised version of Chapter 21 of the PCT International Search and Preliminary Examination Guidelines which was approved by the 16th session of the Meeting of International Authorities, but which has not yet been formally promulgated, pending consultation with the Member States as a whole (see the Annex to document PCT/MIA/16/2). Paragraph references in this report are, unless otherwise stated, to paragraphs in that revised version of Chapter 21.

7. This revised version is compliant with the original since it contains all of the requirements of the original quality framework, together with a number of additional requirements. However, the requirements are regrouped to provide more coherence and consistency following the experience of reporting under the original framework.

8. The framework is made up of an introduction and 8 main sections, each one of which is reported on below (a ninth section contains the requirement to make annual reports on quality management systems). Each section has an introduction covering the main findings from the review of the quality reports, followed, where appropriate, by recommendations for action by the International Authorities or for further study.

Introduction

9. Seven Authorities are using ISO 9001 as normative reference and at least 2 more are working with this standard.

1. Leadership and Policy

10. Almost all of the Authorities have a quality policy established by top management. For a majority of the Authorities, responsibility for the quality management system (QMS) is an integral part of management responsibilities. Most Authorities have one or more bodies with defined responsibility regarding mainly quality management issues and/or support. These bodies are, in most Authorities, also responsible for the effectiveness of the QMS and the progress of continual improvement process, or at least supporting the effectiveness and the continual improvement process.

2. Resources

11. Nearly all of the Authorities have the required quantity of staff to deal with the workflow. The management of the Authorities which do not have sufficient staff are planning to recruit more staff.

12. Almost all of the Authorities have a quantity of staff which maintains the required language facilities.

13. Most of the Authorities fulfil all the requirements of a quantity of skilled administrative staff to support the technical staff and for documentation records.

14. All of the Authorities consider that they now have appropriate IT equipment.

15. All of the Authorities have access to the minimum documentation according to PCT Rule 34.

16. All of the Authorities use guidelines or working manuals in either paper or electronic form or both. These manuals contain the work flow procedures as well as the quality criteria and standards.

17. All of the active Authorities have the training resources to maintain necessary skills in search and examination and to ensure awareness of staff to comply with quality criteria.

18. In all Authorities, two or more departments are responsible for monitoring the various required resources, whether to deal with the demand or to comply with the quality standards.

3. Management of administrative workload

19. The heads of the examination units of all Authorities monitor the examiners' workload as well as the number of search and examination requests, priorities and timeliness. An examiner appointed for each application and his/her supervisor are responsible for timely issue of search and examination reports and their compliance with the quality standard as set by the respective Authority. In addition there are special units in some Authorities, which monitor the number of requests, the workload and timeliness.

20. There are automated systems in most Authorities, which include detailed information on the applications and allow managers to monitor the number of incoming requests for search and examination, deadlines, the number of applications relating to a particular class of IPC, workload of each examiner and so on. The examiners have access to these systems and can monitor deadlines and work stages on the applications. The automated systems, as a rule, have the possibility of sending an alert to the examiners about the deadline for any stage of work on an application. Other Authorities are developing such systems or improving basic systems to provide greater information.

21. Where an automated system is implemented, it is used to monitor fluctuations in requests for search and examination and to manage backlog. The authorized persons in each Authority regularly, usually monthly, prepare reports for the Authority's senior management. In those Authorities where there are special units for this purpose, they also monitor the fluctuations and backlog. On the basis of the information obtained, the management seeks to carry out timely distribution or redistribution of applications among examiners.

4. Quality assurance

22. All Authorities confirmed that they have an internal quality assurance system. There are some differences between Authorities in the order and frequency of search and examination quality control, criteria for quality assessment, reporting forms, preventative measures and channeling feedback to staff.

23. Most Authorities use multilevel control, such as:

(a) quality control carried out in the process of search and examination by an examiner's supervisor or by other examiners; and

(b) later quality control carried out by a special unit.

24. The frequency of quality assessment of reports varies between once a month to once a year in different Authorities.

25. Usually, Authorities use random selection of applications for quality control carried out after the reports have issued. Methods of selecting include checking of one PCT application prepared by each examiner or random sampling of between 10% and 25% of international applications for which reports were issued.

26. Most Authorities reported that they communicate the results of quality control to staff both on individual applications and on statistical analysis.

27. The results of quality control are collected, analyzed and summarized by authorized units of each Authority. On the basis of these results the manuals, guidelines and plans for staff training are developed to overcome identified problems.

28. Some Authorities have special units for verifying the effectiveness of actions taken to correct unsatisfactory search and examination work. In other Authorities this function is performed by the management of the Authority generally.

5. Communication

29. All Authorities reported contact information for those responsible for ensuring best practice, continual improvement and effective communication.

30. The majority of Authorities reported on having means for handling complaints and making corrections. Various approaches were reported on, including:

(a) examiner contact information being made available on documents;

(b) online systems for collecting and distributing customer feedback

(c) receiving and analyzing complaints at the Authority through mail, telephone, email or fax.

(d) conducting meetings, or making themselves available at tradeshows and/or industry and university events.

31. Corrective and preventative action measures are in place at most Authorities, though these systems were not described in great detail in the reports

32. Authorities reported measuring user satisfaction via a wide variety of ways. Half the Authorities discussed conducting user satisfaction surveys, conducting meetings with applicants and/or attorneys. Also most Authorities discussed accepting comments on user satisfaction through online or other means.

33. Most Authorities indicated that they ensured legitimate client needs and expectations were met, but this was not elaborated on in the reports in great detail. Two Authorities reported publishing user satisfaction targets, and four Authorities reported using comments in development and revision of manuals and tools.

34. Most Authorities reported on publishing guidance for users online. Three Authorities reported on publishing physical guides and manuals. Two Authorities reported offering free consultations and three Authorities offer public discussions.

35. Most Authorities have made their quality objectives fully or partially publically available. Two Authorities report that they have chosen to not make them publically available.

36. Most Authorities reported that specific persons or departments within the Authority were responsible for maintaining contact with WIPO and designated and elected offices.

37. Reporting on how the Authorities ensure WIPO feedback is promptly evaluated and addressed was not consistent throughout the reports. Many Authorities were silent on this particular topic, but some reported having PCT or administration departments or individuals who were responsible for responding in a timely manner. One Authority reports having an online secure channel with designated or elected offices for receiving comments or concerns.

6. Documentation

38. Six Authorities have already defined and distributed their Quality Manual as defined in Chapter 21. These are mainly distributed by intranet and a few also have other tools including paper or other forms of electronic distribution. All the Authorities concerned have tools to control document versions.

39. For the rest of the Authorities there are two specific cases:

(a) ones that are currently preparing this documentation but the parts already prepared are distributed; and

(b) others that have different documents that would be in a Quality Manual which are properly distributed, but as independent documents rather than being compiled as a single document.

40. Most Authorities maintain all or nearly all of the types of record referred to in paragraph 21.23. The records most commonly missing related to results of management review, results of reviews of requirements relating to products and search process documentation.

7. Search Process Documentation

41. Almost all respondents require examiners to document the search in some way but there are differences in the extent and use of these records. The differences and similarities can be grouped into three main categories.

(a) *Content* – Most IAs include most of the main elements listed in paragraph 21.24 (databases consulted; keywords, combinations of words and truncations used; language(s) in which the search was carried out; classes and class combinations searched, at least according to the IPC or equivalent; and all search statements used in the databases consulted). There are significant differences in the extent to which internet searches are documented and to which documents viewed are systematically recorded.

(b) *Format* – Although the quality framework makes clear what should be included in the search record, there is no guidance on how it should be presented. The reports show different approaches ranging from "history lists" of search statements to simple unstructured manual records. There is no requirement for International Authorities to conform to a common structure or layout of the search record, which makes it less useful in any eventual exchange between International Authorities.

(c) *Use* – Most Authorities give little description on how the search record is used, probably because neither the quality framework itself, nor the template for annual reports call for this. A number of Authorities specify that the search record is used in a check of the examiners' search, as part of which feedback is given on the examiner's rationale, either in all cases or in samples selected for review.

8. Internal Review

42. The International Authorities report on their processes for internal review of their quality management systems at different levels of detail. Some are very general, others very detailed even adding elements not listed in the template for reporting. This could be considered in a future improvement to Chapter 21 or the template.

43. Almost all Authorities state they have a system of internal review. Few report the optional additional information suggested in the template for reporting, referring rather to details given under the section on “Leadership and Policy”. The main difference perceived between Authorities is the extent to which the internal review is formalized. This, in turn, seems linked to whether ISO 9001 is referred to as a standard or not, since it calls for formal annual review, follow up action and implementation of a PDCA (plan-do-act-check) cycle.

Other Issues Considered

44. While reviewing the International Authorities’ reports on their quality management systems, a number of areas were found where improvements may be desirable in the templates for these reports or in the quality framework itself. However, detailed proposals on these matters have not yet been prepared, pending completion of the recommendations for action more generally.

[Annex II follows]

EXTRACT FROM THE REPORT OF 18TH SESSION OF THE
MEETING OF INTERNATIONAL AUTHORITIES UNDER THE PCT

(reproduced from document PCT/MIA/18/16)

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Quality Framework: Report and Recommendations from the Quality Subgroup

10. Discussions were based on document PCT/MIA/18/2.

11. The Meeting:

(a) noted with approval the report of the quality subgroup set out in the Annex to document PCT/MIA/18/2;

(b) approved the continuation of the subgroup's mandate and requested it to report to the next session of the Meeting on the subjects of:

(i) effective processes and solutions for quality assurance; and

(ii) effective quality improvement measures,

taking into account the comments in paragraphs 12 to 18, below, and any new information presented to the subgroup in the meantime, including the updating of International Authorities' reports on quality management systems which would take place in the second half of 2011;

(c) agreed that the annual reports submitted by the International Authorities should be made publicly available on WIPO's website; and

(d) agreed that the International Bureau should submit a report to the PCT Assembly on the work undertaken in relation to the quality framework, including a reference to the annual reports and annexes comprising the report from the quality subgroup as set out in document PCT/MIA/18/2 and the relevant section of this report.

12. Several Authorities stated that they had found the process of analysis and discussion of the reports to be extremely useful. Effective quality management procedures were felt to be important for the future of the PCT system. It was very beneficial for Authorities to recognize areas where they did not fully comply with the requirements of the quality framework and exchanging information helped to identify opportunities for improvement.

13. The Authorities which had sent representatives to the physical quality subgroup meeting hosted by the Swedish Patent and Registration Office in Stockholm from December 2 to 3, 2010, confirmed that the discussions had been very useful and made a great contribution to the successful discussions using the electronic forum. Face to face discussions had permitted in-depth consideration of issues where there had not previously been sufficient understanding and had been a key factor in organizing and promoting the activities which had taken place after the meeting. Consequently, despite the wish to minimize costs, it was felt that some physical meetings would be important in the future to support the work carried out using the subgroup's electronic forum.

14. Further to the information set out in the Annex to document PCT/MIA/18/2, it was noted that the Authorities had concluded that, in some respects, neither the templates which had been agreed for reports nor the quality framework itself were sufficiently clear to achieve a common understanding in all areas and that the reports had provided significantly different levels of detail in some areas. There was room for further improvement in both, which might well form part of the recommendations of the subgroup to the next session of the Meeting. One Authority expressed concerns about the possible nature of such changes, noting that the templates were already fairly detailed and required a significant effort to collect and present the necessary information. It was hoped that any changes would be of the nature of improvements to clarity rather than necessarily requiring an increased level of detail.

15. One Authority stated that it had found the detailed tables which had been put together by the subgroup to assist its analysis work to be extremely useful.

16. Other issues which required further analysis included greater harmonization of checklists for use in quality management processes and consideration of the appropriate ways to deal with non-conformities with the requirements of the quality framework.

17. Several Authorities expressed their concern over the fact that the revised version of Chapter 21 of the PCT International Search and Examination Guidelines, on which the annual reports were based, had not yet been officially promulgated. The International Bureau confirmed that this was a priority and that the necessary consultation with other Contracting States should be undertaken as soon as possible.

18. Noting the wide range of meetings already scheduled for 2011 in various fora with an interest in various aspects of patent quality, it was concluded that the best timing for a further physical meeting of the quality subgroup would probably be in early 2012, following the submission and initial analysis of the annual update to quality reports by International Authorities. This would allow the meeting to finalize any proposals for improvements to the quality framework and reporting templates based on the additional experience gained from the further reports. It was also emphasized that, in addition to the procedural aspects of quality management which had been the main focus of discussions up to this point, the meeting should also address the question of effective quality improvement measures, notably the development of quality metrics. In this context, it was noted that some details of national quality metrics had been provided by some Authorities as a starting point for discussions in this area.

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[End of Annex II and of document]