E

WIPO

PCT/MIA/17/8
ORIGINAL: English only
DATE: February 2, 2010

WORLD INTELLECTUAL PROPERTY ORGANIZATION
GENEVA

INTERNATIONAL PATENT COOPERATION UNION
(PCT UNION)

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

Seventeenth Session
Rio de Janeiro, February 9 to 11, 2010

QUALITY FRAMEWORK

Document prepared by the International Bureau

SUMMARY

1. International Authorities are invited to discuss issues arising from submitted reports on quality management systems, to review new templates for such reports and to consider the creation of a quality subgroup to provide more effective discussion of quality issues.

REPORTS BY INTERNATIONAL AUTHORITIES

2. Chapter 21 of the PCT International Search and Preliminary Examination Guidelines ("the Guidelines", document PCT/GL/ISPE/1) sets out a quality framework for International Authorities and requires Authorities to submit annual reports on their implementation of quality management systems in accordance with that framework. The reports which have been submitted are available from the private forum of the Meeting of International Authorities on the WIPO website. Authorities are invited to present to the Meeting any aspects of their reports which they consider may be of particular relevance to other Authorities and to discuss the reports of other Authorities.

3. In accordance with paragraph 21.17 of the Guidelines, the Meeting should present a report to the Assembly on progress. The International Bureau proposes that individual reports by International Authorities should again be made available to the public on the WIPO website and that the report to the Assembly should take a similar form to the one presented to the 40th session of the PCT Assembly (document PCT/A/40/3), pointing to the availability of the individual reports, together with any particular statements which the Meeting may wish to include.

Future Reports

4. Annexes I and II contain two new draft templates, prepared by the European Patent Office, for future "initial" and "supplementary" reports respectively. The templates are based on the revised version of Chapter 21 of the PCT International Search and Preliminary Guidelines which was agreed by the Meeting at its 16th session (document PCT/MIA/16/2 and paragraphs 56 to 59 of document PCT/MIA/16/15). The revised Chapter 21 will shortly be circulated for comment by the other Contracting States and, in the absence of adverse comment, will be formally promulgated later this year.

5. The International Bureau proposes that these templates should be provisionally agreed by the Meeting as the basis for future reports, subject to any comments which might be made during the Meeting and the following procedural arrangements:

(a) Each International Authority will use the template for an "initial" report to create a new report on the state of their quality management system at the end of 2010 and again every 5 years.

(b) In intervening years, International Authorities will usually report on changes which have occurred during the year using the "supplementary" template. International Authorities should be free to use the "initial" template in cases where major changes have occurred, but should still attempt to make clear where the most significant changes lie so that other Authorities can attempt to understand and learn effectively.

(c) The templates should be subject to both an initial and an ongoing review by the quality subgroup referred to below, if it is agreed to set this up. The subgroup should be permitted to make any changes to the templates which are agreed by all participants, without the need for confirmation by this Meeting. Such changes should, however, be reported to the Meeting.

FURTHER WORK

Forum for Future Discussions

6. At the sixteenth session of the Meeting, the Swedish Patent and Registration Office proposed a system permitting quality feedback from designated and elected Offices to International Authorities in the following terms (paragraph 6 of document PCT/MIA/16/5):

> "6. The Swedish Patent and Registration Office also proposes the introduction of a quality subgroup under the Meeting of International Authorities with the task to put together a common quality report, from the different initial or annual (21.29-21.30) reports submitted by the different offices, and also make some general recommendations on improvements. The group should be chaired by the International Bureau and consists of all International Authorities' quality contact persons (21.17)."

7. The Meeting "agreed that the Secretariat should, in consultation with the Swedish Patent and Registration Office, establish a suitable electronic forum whereby experts from interested Authorities could undertake discussions of quality-related matters. Progress on the establishment and operation of the forum should be reported to the Meeting at its next session" (paragraph 65 of document PCT/MIA/16/15).

8. The International Bureau notes that the representatives in this Meeting are usually not all experts on quality management issues and agrees that it would be useful to have a forum where detailed quality issues can be discussed more effectively. Consequently, while it has not yet established such forum, it is willing to do so quickly. It is proposed to set up the same "wiki"-based system as has recently been successfully introduced for discussion in a number of WIPO standards task forces. This includes both typical wiki facilities for collaborative drafting and bulletin-board type comments features.

9. However, such electronic discussions are rarely successful unless they either have fairly straightforward, well-understood tasks, or else are used by a group of individuals who already know one another and have been able to discuss the less well-defined aspects and necessary timetables face to face. Also, a strong focus is required in order to drive forward projects which do not have physical meetings which define milestones and require the immediate attention of participants. The International Bureau places a high importance on the development of quality management systems and is willing to provide as much administrative support to such work as possible, but it does not have the practical experience of operating search and examination facilities necessary to drive many of the aspects of the work.

10. Consequently, the following general considerations and working arrangements are suggested:

(a) The quality subgroup should consist of at least one representative from each International Authority and the International Bureau. It is understood that the normal representatives will be experts responsible for the quality management systems for their Offices in their roles as International Authority, but other representatives may be included at any time according to the needs of the discussion.

(b) The subgroup should be free to discuss any aspect of quality management for International Authorities of its own volition, in addition to any questions specifically referred to it by the Meeting or the Assembly.

(c) The subgroup should be permitted, on agreement by all representatives, to adopt recommendations which fall within the scope of Chapter 21 of the International Search and Preliminary Examination Guidelines, as well as amendments to the templates for reporting under Chapter 21 of the Guidelines. Any such recommendations or amendments would be reported to the Meeting. The International Bureau would, where necessary for information, forward such recommendations to the Assembly or otherwise report them to the Contracting States.

(d) If the subgroup considers that changes to Chapter 21 of the Guidelines would be desirable, or that issues of policy are involved falling outside the scope of the existing quality framework it should make recommendations, if these can be agreed, and request appropriate consideration by the Meeting. The International Bureau would, where necessary for information or decision, forward such recommendations to the Assembly or otherwise report them to the Contracting States.

(e) Discussions should usually be conducted informally using an electronic forum. The subgroup may convene physical meetings for all or part of the group, provided that the subgroup agrees that such a meeting is desirable and all participants' Offices are willing to bear the cost of participation in such a meeting or agree that their participation in the meeting is not required.

(f) The International Bureau would be happy to "chair" discussions to the extent of hosting and moderating the electronic forum and to provide a chair for any physical meetings if the subgroup wishes the International Bureau to take on that role. However, the individual tasks undertaken by the subgroup should have an expert leader responsible for driving the discussions forward, who should normally be one of the representatives of the International Authorities.

(g) The subgroup should report progress to the Meeting. It should also prepare a report to the Assembly by June 30 each year (from 2011 onwards), following discussion of the individual reports of the International Authorities by the subgroup and, where relevant, by the Meeting. Such reports should be circulated electronically via the Meeting's electronic forum for final comment by the International Authorities before being submitted to the Assembly.

11. The initial task of such a subgroup would be to define the tasks which it considered necessary for improving the understanding and operation of quality management systems in all International Authorities and to decide whether an initial physical meeting would assist that process. If so requested, the International Bureau would be prepared to host such a meeting in or around September 2010, but it should be considered whether there would instead be benefits in holding it in an Office which was able to demonstrate aspects of quality management systems by reference to its own local implementation.

12. The Meeting is invited to:

(i) discuss the reports which have been submitted by International Authorities on their quality management systems;

(ii) decide what form of report should be sent to the Assembly;

(iii) approve the templates in Annexes I and II for use in preparing future reports, subject to possible further revision by the quality subgroup referred to in item (iv), below;

(iv) approve the creation of a quality subgroup in accordance with the considerations and arrangements in paragraphs 8 to 11, above.

[Annexes follow]

ANNEX I

TEMPLATE FOR REPORTING ACCORDING TO PARAGRAPH 21.29

The Authority should provide general background information relevant to the quality management system (QMS) as set forth in this template.

The descriptions below each main heading of this template should be considered examples of the type and arrangement of information that should be included under each heading. Each Authority may provide additional information beyond that set forth in this template as desired.

Introduction (Paragraphs 21.01 - 21.03)

If applicable, the Authority may at this point indicate any recognised normative reference or basis for their quality management system besides Chapter 21, e.g. ISO 9001, under the heading "Normative Reference for QMS"

e.g. "Normative reference for QMS: ISO 9001, EQS (European Quality System)"

Each authority should then provide at least the following information, under the following headings:

1. Leadership and policy

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

(a) The quality policy established by top management.
(b) The roles and names of those bodies and individuals responsible for the QMS, as delegated by top management.
(c) An organisational 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.

Chapter 21 requirement	Extent of compliance		
	full	part	no
21.04(a) Quality policy available		✓	
21.04(b) Identified roles and names for QMS responsibility	✓		
21.04(c) Organisational chart available	✓		
21.05 Established compatibility of QMS with Chapter 21	✓		
...			
21.27(f) Review contains recommendations for improvement	✓		
21.24 Search process is documented		✓	

21.06 Indicate with reference to the organizational chart those bodies and mechanisms management uses to ensure:
(a) the effectiveness of the QMS; and
(b) that the process of continual improvement progresses.

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
(b) complying with the Authority's QMS.

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.

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);
(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));
(ii) to determine the extent to which Search and Examination work complies with PCT Guidelines (cf. paragraphs 21.25, 21.27(a));
(c) in an objective and transparent way (cf. paragraph 21.25);
(d) using input including information according to paragraphs 21.27 (b)-(f);
(e) recording the results (cf. paragraph 21.28).

2. Resources

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;
(ii) which maintains the technical qualifications to search and examine in the required technical fields; and
(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.

(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.

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;
  (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.

(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.

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.

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.

3. Management of administrative workload

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

4. Quality assurance

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;
  (ii) for channelling feedback to staff.

(b) A system of measurement and collection of data and reporting. Show how the Authority uses the system to ensure the continuous improvement of the established processes.

(c) A system for verifying the effectiveness of actions taken to correct deficient S&E work, eliminate the causes, and to prevent issues from recurring.

5. Communication

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.

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;
  (ii) taking corrective and/or preventative action where appropriate; and
  (iii) offering feedback to users.

(b) A procedure for:
  (i) monitoring user satisfaction and perception; and
  (ii) for ensuring their legitimate needs and expectations are met.

(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.

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

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

6. Documentation

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;
(b) the media on which it is supported (e.g. Internal Publication, Internet, Intranet); and
(c) document control measures taken e.g. version numbering, access to latest version.

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.

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;
(c) training, skills and experience of personnel;
(d) evidence of conformity of processes, resulting products and services in terms of quality standards;
(e) results of reviews of requirements relating to products;
(f) the search and examination processes carried out on each application;
(g) data allowing individual work to be tracked and traced;
(h) records of QMS audits;
(i) actions taken re. non-conforming products, e.g. examples of corrections;
(j) actions taken re. corrective action;
(k) actions taken re. preventative action; and
(l) 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. 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.

8. Internal review

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.

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

9. Arrangements for Authorities to Report to the MIA

21.29 There are two stages in the reporting arrangements. The document up to this point relates to the initial report called for by paragraph 21.29.

[Annex II follows]

ANNEX II

TEMPLATE FOR ANNUAL REPORT ACCORDING TO PARAGRAPH 21.30

This supplemental report relates to the QMS established by

(NAME OF AUTHORITY)

as set forth in our report under PCT/GL/ISPE section 21.29 on

(DATE OF LAST REPORT UNDER 21.29)

and as modified in the supplemental report(s) under PCT/GL/ISPE section 21.30 on

(DATE OF SUPPLEMENTAL REPORT(S) IN WHICH CHANGES WERE PREVIOUSLY INDICATED).

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 template proposed in Annex I, 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.)

[End of Annex II and of document]