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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)

Twelfth Session
Geneva, December 12 to 16, 2005

QUALITY FRAMEWORK:
PROPOSED REPORTING TEMPLATES

Proposals by the European Patent Office (EPO)

INTRODUCTION

1. Chapter 21 of the PCT Guidelines for Search and Examination PCT/GL/ISPE/1 ("Chapter 21"), points 21.17 and 21.18, require International Searching and Preliminary Examining Authorities to submit annual reports to the Meeting of International Authorities (MIA) regarding the implementation of a Quality Management System (QMS), in accordance with the broad requirements of the rest of Chapter 21. The EPO considers that the full potential of such reporting arrangements could best be realized by ensuring that the reports themselves are compiled according to a uniform, common standard. In this regard, a proposal is made for the adoption of two templates, one for each of points 21.17 and 21.18, as set out in Annexes I and II to this document. Before considering the proposed templates, some explanation is needed.

2. There are three potential situations:

(a) The "Authority" is a national patent office applying to become an International Searching Authority (ISA) / International Preliminary Examination Authority (IPEA) under the PCT. This situation falls outside the scope of the reporting arrangements to the MIA under Chapter 21, and although it is not covered by the proposed templates, it is envisaged

that the template set out in Annex I could be used as a basis for the information on QMS required from such candidates.

(b) The "Authority" is already an ISA/IPEA under the PCT and is submitting a report to the MIA on its QMS for the first time. This falls under point 21.17 and is covered by the template of Annex I, designated T21-17.

(c) The "Authority" is already an ISA/IPEA under the PCT, has already submitted a first report to the MIA on its QMS under 21.17, and is now submitting an annual "progress report" under point 21.18. This iscovered by the template of Annex II, designated T21 -18.

3. Thus, the annexed templates are drafted assuming that the respondent is already an International Authority under the PCT.

Data on "Resources" of the Authority, Points 21.05 and 21.06.

4. Both templates assume that data on the minimum requirements for appointment as ISA/IPEA, in particular staffing levels, and documentation resources of the Authority are available to the MIA via the International Bureau and can be consulted together with the reports under 21.17 and 21.18. Therefore, T21-17 does not ask for this basic information, but rather requires explanation of the mechanisms for adapting staffing levels etc. according to changes in workload. In the same way, T21-18 only requires an explanation of the changes in staffing levels etc. since the last report. In addition, T21-18 requires some summarization of the results achieved during the same period.

Numbered Points under Chapter 21

5. The templates refer to only those numbered points which would benefit from a response according to a common standard, for comparative purposes.

6. The Meeting is invited to consider the proposed templates set out in Annexes I and II.

[Annexes follow]

ANNEX I

TEMPLATE T21-17

(FOR RESPONSES TO PCT/GL/ISPE/1, CHAPTER 21.17, STAGE 1 REPORTING)

Responses to some numbered points of Chapter 21 are most useful if formulated according to a common standard. This document provides guidance to IA's for these points. It applies to the initial report under Stage 1 according to chapter 21.17 of PCT/GL/ISPE/1. Each point is accompanied by a heading and text guiding the response to that particular point.

INTRODUCTION

The introduction should give general information about the Authority's Quality Management System (QMS). It should include the following information, if applicable:

(i) recognized normative reference or basis for quality management system besides Chapter 21 e.g. ISO 9000.

21.1 Consistency and commonality of international search and examination (S&E) work

The following should also be described:

(i) internal measures taken to minimize inconsistencies in S&E work within the organization.

(ii) participation in active cooperation programs for minimizing inconsistencies of S&E work with other IA's.

21.2 Statement of compliance

This should be a brief statement showing to what extent the organization fulfils the requirements of Chapter 21. In particular, those partsof Chapter 21 which are not currently complied with should be discussed.

QUALITY MANAGEMENT SYSTEM (QMS)

21.3 Status of QMS

This should indicate whether, and to what extent,

(i) a QMS is in place which sets out basic requirements with regard to

(a) resources,

(b) administrative procedures,

(c) feedback and communication channels

required to underpin S&E;

(ii) a documented quality assurance scheme for monitoring compliance with

(a) Chapter 21 requirements and

(b) PCT Guidelines for ISPE

is in place as part of the QMS.

This section should also include an organigram showing the organizational units responsible for the points under 21.3. It should be referred to in the report as necessary.

21.4 Measures taken to meet common QMS requirements specified by Chapter 21

The response to this point could, if necessary, include a summary of the most significant measures taken to meet the common QMS requirements as laid down in Chapter 21. These measures should be specified in more detail in response to the points below.

RESOURCES

21.5 Workload management, staffing, equipment, documentation and training

What steps are taken to ensure that the following resources and infrastructure can be accommodated to changes in workload?

(a) Staffing levels for S&E.

(b) Staffing levels for administration.

(c) Equipment and facilities supporting S&E.

(d) Documentation supporting S&E (c.f. Rule 34).

(e) Work manuals.

(f) Training and development for skills acquisition and quality awareness.

(g) If not covered under points (a) to (f), describe other means for monitoring and identifying resources necessary to deal with demand and comply with quality standards for S&E.

ADMINISTRATION

21.6 Practices and procedures for handling requests for S&E and related functions (e.g. data entry, classification)

Describe the following practices and procedures:

(a) Control mechanisms to ensure timely issue of S&E reports.

(b) Control mechanisms to cope with fluctuations in demand and for backlog management.

(c) Systems for handling complaints, taking corrective action, and taking preventative action; measuring user satisfaction and perception; ensuring needs and legitimate expectations of users are met.

QUALITY ASSURANCE (QA)

21.7 Procedures for timely issue of S&E reports to PCT/GL/ISPE quality standards

Describe the following procedures:

(a) The internal quality assurance system for self assessment, in terms of:

(i) verification, validation and monitoring of search and examination work for compliance with S&E guidelines;

(ii) channeling the results as feedback to staff.

(b) Systems for measuring, recording, monitoring and analysing performance of the QMS, to assess it's conformity with the requirements of Chapter 21.

(c) Systems for verifying the effectiveness of actions taken to:

(i) address deficiencies;

(ii) prevent issues from recurring.

(d) Systems for ensuring the continuous improvement of established processes.

FEEDBACK ARRANGEMENTS

21.8 Arrangements for performance improvement and continual improvement.

Describe how the following measures are undertaken:

(a) Communication of results of internal QA process to staff to

(i) ensure that necessary corrective action is taken;

(ii) disseminate best practice;

(iii) adopt best practice.

(b) Provision of effective communication with

(i) WIPO;

(ii) designated offices;

(iii) elected offices;

allowing prompt feedback from them and allowing evaluation and addressing of potential systemic issues.

COMMUNICATION AND GUIDANCE TO USERS

21.9 Arrangements for communication with users

Describe the arrangements in place to provide:

(a) Communication channels for dealing promptly with enquiries and enabling appropriate two-way communication between applicants and examiners.

(b) Concise and comprehensive guidance and information to users (particularly unrepresented applicants) on the S&E process using the website of your Authority, guidance literature, and other means.

INTERNAL REVIEW

21.10 Establishment of QMS and compliance with requirements.

(a) Describe the internal review arrangements in place to determine the extent to which:

(i) the QMS is based on the requirements of Chapter 21;

(ii) the Authority subjects the QMS to the requirements for review under Chapter 21;

(iii) the Authority complies with the requirements of PCT/GL/ISPE/1.

(b) Describe the means in place to demonstrate whether the requirements and guidelines under 21.10(a) are:

(i) being applied consistently and effectively;

(ii) undertaken annually.

21.11 Internal review mechanism and reporting system.

State the department responsible for the internal review mechanism and the reporting system which ensures compliance with the requirements of the PCT/GL/ISPE/1 and of the QMS itself.

MONITORING AND MEASURING

21.12 Input to reviews

State which of the following are used for input to each review, and what arrangements are in place to collect the input data.

(a) Information on conformity with: (i) QMS requirements; (ii) PCT/GL/ISPE.

(b) Information on: (i) corrective action; (ii) preventative action to eliminate the cause of non-compliance.

(c) Information on follow-up action from previous reviews.

(d) Information on the effectiveness of: (i) The QMS itself; (ii) its processes.

(e) Feedback from the customer including: (i) designated Offices; (ii) elected Offices; (iii) applicants; (iv) other users.

(f) Recommendations for improvement.

21.13 Arrangements for monitoring, recording and measurement

Indicate:

(a) Arrangements established for monitoring, recording and measuring compliance: (i) with the QMS requirements; (ii) with PCT/GL/ISPE/1.

(b) Arrangements to measure customer satisfaction including views of: (i) designated Offices; (ii) elected Offices; (iii) applicants and their representatives; (iv) other users.

ANALYSIS

21.14 Analysis, presentation of results to management and identification of improvements

Briefly describe:

(a) how the measured data of 21.13 are analysed to determine whether:

(i) QMS requirements;

(ii) PCT/GL/ISPE/1 guidelines;

are being met:

(b) how and when results are presented to senior management to:

(i) convey an objective appreciation of performance against requirements of the QMS and of PCT/GL/ISPE/1;

(ii) identify opportunities for improvement;

(iii) identify the need for changes.

IMPROVEMENT

21.15 Continuous improvement and corrective action

Describe the systems in place to:

(a) continually improve performance against QMS requirements and review the effectiveness of the QMS.

(b) identify corrective action required, promptly take such action, and eliminate the cause of any failure to comply with requirements of the QMS and PCT/GL/ISPE which prompted this corrective action.

[Annex II follows]

ANNEX II

TEMPLATE T21-18

(FOR RESPONSES TO PCT/GL/ISPE/1, CHAPTER 21.18, STAGE 2 REPORTING)

Responses to some numbered points of Chapter 21 are most useful if formulated according to a common standard. This document provides guidance to IA's for these points. It applies to the annual report under Stage 2 according to chapter 21.18 of PCT/GL/ISPE/1. Each point is accompanied by a heading and text guiding the response to that particular point.

INTRODUCTION

The introduction should summarize the changes that have taken place since the last report under chapter 21.17 or 21.18. In particular, general information about the continuing implementation and development of the Authority's Quality Management System (QMS) should be given, including the following points if applicable:

(i) Summarized results of any comparisons with a recognized normative reference or basis for a QMS besides Chapter 21 (e.g. ISO 9000), and summarized results of any reviews carried out according to this reference or basis.

21.1 Consistency and commonality of international search and examination (S&E) work

The following should also be discussed:

(i) results of internal measures taken since the last report to minimize inconsistencies in S&E work within the organization;

(ii) results of participation in active co-operation programs for minimizing inconsistencies of S&E work with other IA's.

21.2 Statement of compliance

This should be a brief statement showing to what extent the organization now fulfils the requirements of Chapter 21, compared with the previously reported situation. In particular, progress made and lessons learned regarding those parts of Chapter 21 which were not complied with at the last report, should be discussed.

QUALITY MANAGEMENT SYSTEM (QMS)

21.3 Status of QMS

This should indicate the progress made since the last report regarding whether, and to what extent:

(i) a QMS is in place which sets out basic requirements with regard to:

(a) resources;

(b) administrative procedures;

(c) feedback and communication channels;

required to underpin S&E;

(ii) a documented quality assurance scheme for monitoring compliance with:

(a) Chapter 21 requirements;

(b) PCT Guidelines for ISPE;

is in place as part of the QMS.

This section should also include an up-to-date organigram showing the organizational units responsible for the points under 21.3, and highlighting the changes made since the last report. It should be referred to in the present report as necessary.

21.4 Measures taken to meet common QMS requirements specified by Chapter 21

If necessary, summarize the most significant measures taken since the last report to meet the common QMS requirements as laid down in Chapter 21. These measures should be specified in more detail in response to the points below.

RESOURCES

21.5 Workload management, staffing, equipment, documentation and training

Describe how and which changes in workload were identified since the last report, and how the following resources were adapted to accommodate these changes.

(a) Staffing levels for S&E.

(b) Staffing levels for administration.

(c) Equipment and facilities supporting S&E.

(d) Documentation supporting S&E (c.f. Rule 34).

(e) Work manuals.

(f) Training and development for skills acquisition and quality awareness.

(g) If not covered under points a)-f), describe any further, newly-introduced means for monitoring and identifying resources necessary to deal with demand and comply with quality standards for S&E.

ADMINISTRATION

21.6 Practices and procedures for handling requests for S&E and related functions (e.g. data entry, classification)

Show to what extent the following practices and procedures were implemented or modified since the last report. Provide results obtained through their implementation, comparing them with the previous report. if possible.

(a) Control mechanisms to ensure timely issue of S&E reports.

(b) Control mechanisms to cope with fluctuations in demand and for backlog management.

(c) Systems for handling complaints, taking corrective action, and taking preventative action; measuring user satisfaction and perception; ensuring needs and legitimate expectations of users are met.

QUALITY ASSURANCE (QA)

21.7 Procedures for timely issue of S&E reports to PCT/GL/ISPE quality standards

Show how the following procedures were implemented in the period since the last report. Highlight important changes in the procedures themselves and any significant results over this period.

(a) The internal quality assurance system for self assessment, in terms of:

(i) verification, validation and monitoring of search and examination work for compliance with S&E guidelines;

(ii) channeling the results as feedback to staff.

(b) Systems for measuring, recording, monitoring and analyzing performance of the QMS, to assess it’s conformity with the requirements of Chapter 21.

(c) Systems for verifying the effectiveness of actions taken to:

(i) address deficiencies;

(ii) prevent issues from recurring.

(d) Systems for ensuring the continuous improvement of established processes.

FEEDBACK ARRANGEMENTS

21.8 Arrangements for performance improvement and continual improvement

Describe how the following measures were implemented in the period since the last report. Highlight any important changes in the procedures themselves and any significant results over this period.

(a) Communication of results of internal QA process to staff to:

(i) ensure that necessary corrective action is taken;

(ii) disseminate best practice;

(iii) adopt best practice.

(b) Provision of effective communication with:

(i) WIPO;

(ii) designated offices;

(iii) elected offices;

allowing prompt feedback from them and allowing evaluation and addressing of potential systemic issues.

COMMUNICATION AND GUIDANCE TO USERS

21.9 Arrangements for communication with users

Describe important changes in, the following arrangements since the last report. Highlight any significant results achieved.

(a) Communication channels for dealing promptly with enquiries and enabling appropriate two-way communication between applicants and examiners.

(b) Concise and comprehensive guidance and information to users (particularly unrepresented applicants) on the S&E process using the website of your Authority, guidance literature, and other means.

INTERNAL REVIEW

21.10 Establishment of QMS and compliance with requirements

(a) Describe progress made over the past reporting period in implementing or applying the internal review arrangements as required by chapter 21.10. Discuss the following arrangements for determining the extent to which:

(i) the QMS is based on the requirements of Chapter 21;

(ii) the Authority subjects the QMS to the requirements for review under Chapter 21,

(iii) the Authority complies with the requirements of PCT/GL/ISPE.

Highlight important changes in these arrangements and significant results achieved.

(b) Describe progress made since the last report regarding implementing or applying means to demonstrate whether the requirements and guidelines under 21.10a) are:

(i) being applied consistently and effectively;

(ii) undertaken annually.

Provide the results obtained during the past reporting period

21.11 Internal review mechanism and reporting system.

Describe changes in the year under review regarding responsibility for the internal review mechanism and the reporting system for ensuring compliance with the requirements of the PCT/GL/ISPE/1 and of the QMS. For example, creation of new departments or re-definition of responsibilities.

MONITORING AND MEASURING

21.12 Input to reviews

State which of the following were used for input to any review which took place since the last report, what data were collected in each case, and what means were used to collect them.

(a) Information on conformity with: (i) QMS requirements; (ii) PCT/GL/ISPE/1.

(b) Information on: (i) corrective action; (ii) preventative action to eliminate the cause of non-compliance.

(c) Information on follow-up action from previous reviews.

(d) Information on the effectiveness of: (i) the QMS itself; (ii) its processes.

(e) Feedback from the customer including: (i) designated Offices; (ii) elected Offices; (iii) applicants; (iv) other users.

(f) Recommendations for improvement.

21.13 Arrangements for monitoring, recording and measurement

Indicate how the following were achieved in the period since the last report, and give figures to quantify the monitoring, recording and measurement which took place.

(a) Monitoring, recording and measuring compliance: (i) with the QMS requirements; (ii) with PCT/GL/ISPE.

(b) Measuring customer satisfaction including views of: (i) designated Offices; (ii) elected Offices; (iii) applicants and their representatives; (iv) other users.

ANALYSIS

21.14 Analysis, presentation of results to management and identification of improvements

Briefly describe:

(a) How the measured data of 21.13 were analyzed in the period since the last report to determine whether: (i) QMS requirements; (ii) PCT/GL/ISPE guidelines; were met.

(b) How and when during the same period results were presented to senior management to:

(i) convey an objective appreciation of performance against requirements of the QMS and of PCT/GL/ISPE/1;

(ii) identify opportunities for improvement;

(iii) identify the need for changes.

(c) The results themselves.

IMPROVEMENT

21.15 Continuous improvement and corrective action

Describe how the systems in place to:

(a) continually improve performance against QMS requirements and review the effectiveness of the QMS.

(b) identify corrective action required, promptly take such action, and eliminate the cause of any failure to comply with requirements of the QMS and PCT/GL/ISPE which prompted this corrective action,

were used during the period since the last report, and the results obtained.

[End of Annexes and of document]