

C. PCT 1523

January 8, 2018

Madam,
Sir,

Proposed Modifications to Chapter 21 of the International Search and Preliminary Examination Guidelines

This Circular is addressed to your Office in its capacity as a receiving Office, International Searching Authority, International Preliminary Examining Authority and/or designated or elected Office under the Patent Cooperation Treaty (PCT). It is also being sent to certain non-governmental organizations representing users of the PCT System.

The Quality Subgroup of the Meeting of International Authorities under the PCT, at its seventh informal meeting in February 2017, discussed proposed modifications to strengthen the requirements for quality management systems in Chapter 21 of the International Search and Preliminary Examination Guidelines “the Guidelines”. These discussions are summarized in paragraphs 13 to 19 of the Summary by the Chair, set out in Annex II to document PCT/MIA/24/15; paragraphs 18 and 19 outline the recommendations of the Subgroup, as follows:

“18. The Subgroup recommended that the International Bureau should issue a Circular to consult Offices in their capacity as a receiving Office, International Searching and Preliminary Examining Authority and/or designated or elected Office, and organizations representing users of the PCT System on the changes proposed in the Annex to the paper, incorporating the drafting modifications referred to in paragraph 16 (*of Annex II to document PCT/MIA/24/15*), above.

“19. The Subgroup recommended the removal of the requirement for annual reports on quality to be submitted to the PCT Assembly.”

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In line with the above recommendations, this Circular proposes modifications to Chapter 21 of the Guidelines, which are set out in the Annex. The aim of these modifications is to provide stronger requirements for the quality management systems of International Searching and Preliminary Examining Authorities. It is proposed that certain optional recommendations relating to overarching aims of quality management systems should become mandatory requirements. Other recommendations covering the implementation of these aims will, however, remain optional, giving International Searching and Preliminary Examining Authorities flexibility on how to put the overarching aims into effect.

The proposed modifications also remove the requirement for annual reporting to the PCT Assembly on the establishment of quality management systems, as recommended by the Subgroup. In this regard, all International Authorities (other than those which have recently been appointed by the PCT Assembly) have established quality management systems for international search and preliminary examination and have been reporting on quality management annually for several years. These quality management reports are made available on the WIPO website. Furthermore, updates have been made to reflect terminology in the latest version of ISO 9001. In particular, the proposed modifications remove the term "Quality Manual" as part of the reference material to document the procedures and processes that affect the quality of work at an Authority since this term is not referred to in ISO 9001:2015.

You are invited to provide comments to the International Bureau on the proposed modifications. Replies should be sent by February 16, 2018, preferably by e-mail to the PCT Business Development Division: pct.bdd@wipo.int.

Yours sincerely,



John Sandage
Deputy Director General

Enclosure: Annex – Proposed Modifications to Chapter 21 of the International Search and Preliminary Examination Guidelines

**PART VII
QUALITY**

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

Introduction

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

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 Authority ~~should~~ shall use as a model for establishing its individual quality scheme.

Rule 36.1(iv) and 63.1(v)

21.03 Each Authority ~~should~~ shall 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 each Authority is responsible for the development and implementation of a Quality Management System (QMS). Top management ~~should~~ shall establish a quality policy for the Authority and it ~~should~~ shall ~~delegate~~ specify responsibilities for the QMS and document these in an organizational chart.

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

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

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

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

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

2. Resources

21.10 Each 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 Guidelines. To those ends, the Authority should have:

– *Sufficient Human Resources:*

(i) 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;

(ii) 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;

– *Sufficient Material Resources:*

(iii) appropriate equipment and facilities, such as IT hardware and software, to support the search and examination process;

(iv) 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;

(v) 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;

– *Sufficient Training Resources:*

(vi) 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

– *Oversight over its Resources:*

(vii) 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

21.11 Each 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:

(i) effective control mechanisms regarding timely issue of search and examination reports to a quality standard as set by the Authority; and

(ii) appropriate control mechanisms regarding fluctuations in demand and backlog management.

4. Quality Assurance

21.12 ~~In accordance with these Guidelines, each~~ Each Authority ~~should~~ shall have procedures regarding timely issue of search and examination reports of a ~~high~~ quality ~~standard in accordance with these Guidelines~~. Such procedures ~~should~~ shall include:

(i) 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 channeling feedback to staff;

(ii) 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: and

(iii) a system for verifying the effectiveness of actions taken to address deficiencies and to prevent issues from recurring.

Such procedures may also include the use of checklists, either to verify the quality ~~standard~~ of search and examination reports in accordance with these Guidelines before those reports are issued and/or to monitor ~~that the~~ quality ~~standard~~ as part of a post-issue review process.

5. Communication

Inter-Authority Communication

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

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

Communication and guidance to users:

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

(i) an appropriate system for handling complaints and making corrections, and taking corrective and/or preventative action where appropriate and offering feedback to users.

(ii) a procedure for monitoring user satisfaction and perception and for ensuring their legitimate needs and expectations are met.

(iii) 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.

~~(iv) the~~ The Authority should make its goals in terms of quality publicly available for the users.

Communication with WIPO and designated and elected Offices

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

6. Documentation

21.17 The QMS of each 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.

21.18 Therefore the Authority ~~should~~ shall 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 reference it is to be indicated where instructions on the procedures to be followed may be found.

21.19 The following list indicates the items which are considered to be the type of content which should be documented ~~of a Quality Manual~~:

- (i) the quality policy of the Authority including a clear statement of commitment to the QMS from top management;
- (ii) the scope of the QMS, including details of and justification for any exclusions;
- (iii) the organizational structure of the Authority and the responsibilities of each of its departments;
- (iv) 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;
- (v) the resources available for carrying out the processes and implementing the procedures; and
- (vi) a description of the interaction between the processes and the procedures of the QMS.

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

- (i) a definition of which documents are kept and where they are kept
- (ii) results of management review;
- (iii) training, skills and experience of personnel;
- (iv) evidence of conformity of processes, resulting products and services in terms of quality standards;
- (v) results of reviews of requirements relating to products;
- (vi) the search and examination processes carried out on each application;
- (vii) data allowing individual work to be tracked and traced;
- (viii) records of QMS audits;
- (ix) actions taken re. non-conforming product, e.g. examples of corrections;
- (x) actions taken re. corrective action;
- (xi) actions taken re. preventative action; and
- (xii) search process documentation as set out in Section 7.

7. Search process documentation

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

- (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; and
- (v) a listing of all search statements used in the databases consulted.

(vi) each Authority should further document at least for internal purposes special cases such as:

- (vii) limitation of search and its justification;
- (viii) lack of clarity of the claims; and
- (ix) lack of unity.

8. Internal Review

21.22 In addition to establishing a quality assurance system for checking and ensuring compliance with the requirements set out in its QMS, each Authority ~~should~~ shall establish its own internal review arrangements to determine the extent to which it has established a QMS ~~based on~~ aligned with the above model and the extent to which it is complying with the QMS requirements and these Guidelines. The reviews ~~should~~ shall be objective and as transparent as possible so as to demonstrate whether or not those requirements and guidelines are being applied consistently and effectively and ~~should~~ shall be undertaken at least once a year.

21.23 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.

21.24 The input to each review should include information on:

- (i) conformity with the QMS requirements and these Guidelines;
- (ii) any corrective and preventative action taken to eliminate the cause of non-compliance;
- (iii) any follow-up action from previous reviews;
- (iv) the effectiveness of the QMS itself and its processes;
- (v) feedback from customers, including designated and elected Offices as well as applicants; and
- (vi) recommendations for improvement.

21.25 Each Authority shall ~~Suitable arrangements should be~~ established a process for monitoring, recording and measuring compliance with the QMS requirements and these Guidelines.

9. Arrangements for authorities to report to MIA

21.26 There are two stages in the reporting arrangements.

(a) *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.~~

(b) *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.

21.27 The reports submitted by Authorities shall be made available by the International Bureau on WIPO's website.

10. Future developments

21.28 Proposals for future changes to the framework set out in this chapter ~~should~~ shall be made available by the International Bureau for comment by interested parties prior to adoption.

[End of Annex and of Circular]