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Patent Cooperation Treaty (PCT)

Common Quality Framework for International Search and Preliminary Examination

INITIAL REPORT ON QUALITY MANAGEMENT SYSTEMS

prepared by China National Intellectual Property Administration

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)

In this introduction, each Authority should include a summary of all changes to their quality management system that have taken place since the previous report on their Quality Management System, and any other matters considered to be interest in relation to quality management.

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

For example: "Normative reference for QMS: ISO 9001, EQS (European Quality System)"

Each Authority should then provide at least the information indicated in the descriptive boxes, under the following headings. Authorities may include process charts if this would facilitate the understanding of an aspect of the report.

The China National Intellectual Property Administration (CNIPA) -has been dedicating to improve the quality of our PCT products and services, including the International Search Reports (ISRs), the Written Opinions of the International Searching Authority and the International Preliminary Examination Reports (IPERs). With the application of quality management measures, the great performance concerning time limit control and correctness of ISR and IPER has been achieved.

In order to achieve higher examination quality and efficiency, the CNIPA has adjusted the quality management system in 2022, and strengthened the overall management of quality assurance and examination guidance in the same technical field by the examination departments. The CNIPA has increased PCT examiners by organizing qualification certification. The CNIPA continued to hold Patent Search Contest to improve the examiners' search ability. Patent Examination Guidelines of CNIPA was comprehensively revised and put into practice on Jan.20, 2024 in order to support the implementation of the Implementing Regulations of the Patent Law. The Patent Search Manual in the technical fields of AI, 5G/6G communication etc. was issued to improve the examiners' search ability.

The Patent Intelligent Examination and Search System (I-System) was launched on Jan. 2023 in CNIPA, which uses modern information technologies such as artificial intelligence, big data, cloud computing to achieve core functions. I-System includes PCT receiving module and PCT international phase examination module.

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 specified by top management.

(c) An organizational chart showing all those bodies and individuals responsible for the QMS.

(a) The CNIPA aims to encourage invention-creation, and handles all applications according to the law and in conformity with the requirements of objectivity, fairness, accuracy and timeliness, and improves examination quality continuously, in order to ensure standards implementation consistency, examination conclusion correctness.

(b) Quality Management System (QMS) has been established since 1990s in order to ensure the compliance of our products with the PCT Treaty and Regulations.

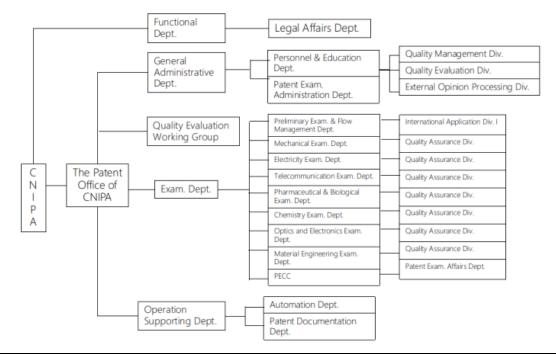
Deputy Commissioner, entitled by Commissioner in CNIPA takes charge of the overall QMS. He is responsible for the administrative and policy direction of examination quality. Under the Deputy Commissioner's instructions, examination quality management of PCT is operated by several organizations.

The Quality Management Division under the Patent Examination Administration Department is responsible for implementing and maintaining the QMS, and defining the quality standards for search and examination. The Quality Evaluation Division under the Patent Examination Administration Department and the Quality Evaluation Working Group, reporting directly to the deputy commissioner of the CNIPA, are in charge of evaluating the compliance of products with these quality standards. The External Opinion Processing Division under the Patent Examination Administration Department is mainly responsible for dealing with user complaints and feedback, together with the related departments, and carrying out user satisfaction surveys.

The Quality Assurance Division of each examination department, established at the beginning of 2015, is responsible for monitoring and managing the process quality to continuously improve the quality of examination together with other quality management officers in the department, and is also responsible for providing quality assurance, examination guidance and training for Patent Examination Cooperation Centers (PECC) in the same technical field. Automation Department and Documentation Department provide the indispensable sources for the search and examination work, such as equipment, facilities and databases etc. The Personnel &

Education Department provides training for the PCT examiners. All these departments work together to ensure effectiveness of the QMS.

(c)



21.05 Indicate (e.g. by means of a table) 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).

[Sample table, to be amended as necessary]

| Chapter 2 | Extent of compliance | | | | |
|-----------|-------------------------|--|------|------|----|
| | | | full | part | no |
| 21.04 | (a) | Quality policy available | ✓ | | |
| | (b) | Identified roles and names for QMS responsibility | ✓ | | |
| | (c) | Organizational chart available | ✓ | | |
| 21.05 | | Established compatibility of QMS with Chapter 21 | ✓ | | |
| 21.06 | (a) | Mechanisms to ensure effectiveness of the QMS | ✓ | | |
| | (b) | Control of the continual improvement process | ✓ | | |
| 21.07 | (a) | Communication of management about this standard to staff | ✓ | | |
| | (b) | The PCT Guidelines are in line with the Authority's QMS | ✓ | | |
| 21.08 | (a) | Management reviews take place | ✓ | | |
| | (b) | Quality objectives are reviewed | ✓ | | |

| Chapter 21 requirement | | | | Extent of compliance | | |
|------------------------|-------|-----|---|----------------------|------|----|
| | | | | full | part | no |
| | | (c) | Communication of quality objectives to the relevant staff at the Authority | ~ | | |
| 21.09 | | (a) | Performance of a yearly internal review of the QMS in/to | ✓ | | |
| | | (b) | determine the extent to which the QMS is aligned with Chapter 21 | ~ | | |
| | | | determine the extent to which search and examination (S&E) complies with PCT Guidelines | ~ | | |
| | | (c) | an objective and transparent way | ✓ | | |
| | | (d) | using input incl. information according paragraph 21.24 | ✓ | | |
| | | (e) | recording the results | ✓ | | |
| 21.10 | | | Risk and opportunities are addressed that can affect the QMS and the conformity of search and examination | ~ | | |
| 21.13 | | | Arrangements for establishing risk-based practices to | ✓ | | |
| | (i) | (a) | understand issues that affect its ability to achieve intended results of the QMS | ~ | | |
| | | (b) | understand the needs and expectations of interested parties | ✓ | | |
| | (ii) | | identify risks and opportunities related to the performance of the QMS as a basis for planning | ~ | | |
| | (iii) | | plan and implement actions to address risks and opportunities | ~ | | |
| | (iv) | | check the effectiveness of the actions taken | ✓ | | |
| | (v) | | continuously update risks and opportunities. | ✓ | | |
| 21.15 | | | Assurance to monitor and adapt to actual workload | ✓ | | |
| | (i) | | Infrastructure in place to ensure that a quantity of staff | ✓ | | |
| | 1 | (a) | sufficient to deal with the inflow of work | ✓ | 1 | |
| | | (b) | which maintains technical qualifications to S&E in all technical fields | ~ | | |
| | | (c) | which maintains the language facilities to understand languages according to Rule 34 | ~ | | |
| | (ii) | | Infrastructure to provide a quantity of skilled administrative staff | ~ | | |
| | | (a) | at a level to support the technically qualified staff | ✓ | | |
| | | (b) | for the documentation of records | ✓ | | |
| | (iii) | | Ensuring appropriate equipment to carry out S&E | ✓ | 1 | |
| | (iv) | | Ensuring documentation according to Rule 34 | ✓ | | |

| Chapte | apter 21 requirement | | | | Extent of compliance | |
|--------|----------------------|-----|---|------|----------------------|----|
| | | | | full | part | no |
| | (v) | (a) | Instructions to help staff understand and act according to the quality criteria and standards | ~ | | |
| | | (b) | Instructions to follow work procedures accurately and they are kept up-to-date. | ~ | | |
| | (vi) | (a) | Training and development program to ensure and maintain necessary skills in search and examination | ~ | | |
| | | (b) | Training and development program to ensure awareness of staff to comply with the quality criteria and standards. | ~ | | |
| | (vii) | (a) | System in place for monitoring resources required to deal with demand | ~ | | |
| | | (b) | System in place for monitoring resources required to comply with the quality standards in S&E | ~ | | |
| 21.16 | (i) | | Control mechanisms to ensure timely issue of S&E reports | ✓ | | |
| | (ii) | | Control mechanisms regarding fluctuations in demand and backlog | ~ | | |
| 21.17 | (i) | | Internal quality assurance system for self-assessment | ✓ | | |
| | | (a) | for compliance with S&E Guidelines | ✓ | | |
| | | (b) | for channeling feedback to staff | ✓ | | |
| | (ii) | | System for measurement of data and reporting for continuous improvement | ~ | | |
| | (iii) | | System for verifying the effectiveness of actions taken to correct deficient S&E work, eliminate the causes and prevent issues from recurring | ~ | | |
| 21.19 | | (a) | Contact person helping identify best practice between Authorities | ~ | | |
| | | (b) | Contact person fostering continual improvement | ✓ | | |
| | | (c) | Contact person providing for effective communication with other Authorities for feedback and evaluation | ~ | | |
| 21.20 | (i) | (a) | Appropriate system for handling complaints | ~ | | |
| | | (b) | Appropriate system for taking preventive/corrective actions | ~ | 1 | |
| | | (c) | Appropriate system for offering feedback to users | ~ | | |
| | (ii) | (a) | A procedure for monitoring user satisfaction & perception | ~ | | |
| | | (b) | A procedure for ensuring their legitimate needs and expectations are met | ~ | | |
| | (iii) | | Clear and concise guidance on the S&E process for the user | ✓ | 1 | |

| Chapter 21 requirement | | | | Extent of compliance | | |
|------------------------|--------|-----|---|----------------------|------|----|
| | | | | full | part | no |
| | | | Indication where and how the Authority makes its quality objectives publicly available | ~ | | |
| 21.21 | | | Established communication with WIPO and designated and elected Offices | ~ | | |
| 21.22 | | | QMS of Authority clearly described and documented | ✓ | | |
| 21.23 | | (a) | Material making up the reference of quality procedures and processes for staff and management has been prepared and distributed | ~ | | |
| | | (b) | Media available to support the reference material | ✓ | | |
| | | (c) | Document control measures are taken | ✓ | | |
| 21.24 | | | Items which should be documented in the reference of quality procedures and processes | ~ | | |
| | (i) | | Quality policy of the Authority and commitment to QMS | ✓ | | |
| | (ii) | | Scope of QMS | ✓ | | |
| | (iii) | | Organizational structure and responsibilities | ✓ | | |
| | (iv) | | Documented processes carried out in the Authority | ✓ | | |
| | (v) | | Resources available to carry out processes and implementing the procedures | ~ | | |
| | (vi) | | Description of the interaction between the processes and the procedures of the QMS. | ~ | | |
| 21.25 | (i) | | Records of which documents are kept and where they are kept | ~ | | |
| | (ii) | | Records of results of management review | ✓ | | |
| | (iii) | | Records about training, skills and experience of staff | ✓ | | |
| | (iv) | | Records of evidence of conformity of processes, resulting products and services in terms of quality standards | ~ | | |
| | (v) | | Records of results of reviews of requirements relating to products | ~ | | |
| | (vi) | | Records of the S&E process carried out on each application | ✓ | | |
| | (vii) | | Record of data allowing individual work to be tracked | ✓ | | |
| | (viii) | | Records of QMS audits | ✓ | | |
| | (ix) | | Records on actions taken re. non-conforming products | ✓ | | |
| | (x) | | Records on actions taken re. corrective actions | ✓ | | |
| | (xi) | | Records on actions taken re. preventive actions | ✓ | | |
| | (xii) | | Records referring to search process documentation | ✓ | | |

| Chapte | Extent of compliance | | | | |
|-----------------|----------------------|---|------|------|----|
| | | | full | part | no |
| 21.26 | (i) | Recording of the databases consulted during search | ✓ | | |
| | (ii) | Recording of keywords, combination of words and truncations during search | ~ | | |
| | (iii) | Recording of the languages used during search | ~ | | |
| | (iv) | Recording of classes and combinations thereof consulted during search | ~ | | |
| | (v) | Recording of a listing of all search statements used in databases consulted | ~ | | |
| | (vi) | Records about other information relevant to the search | ✓ | | |
| | (vii) | Records about limitation of search and its justification | ✓ | | |
| | (viii) | Records about lack of clarity of the claims | ✓ | | |
| | (ix) | Records about lack of unity | ✓ | | |
| 21.27 | | Report on its own internal review processes | ✓ | | |
| 21.28- 21.30 | | Additional information on further inputs to its internal reviews | ~ | | |
| 21.31 | | Initial report called for by paragraph 21.31 | ✓ | | |

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.

(a) The Quality Management Division under the Patent Examination Administration Department is responsible for implementing and maintaining the QMS, to ensure the effectiveness of the QMS.

(b) The Quality Management Division under the Patent Examination Administration Department is responsible for defining the quality <u>evaluation</u> standards for search and examination and establishing effective measures to ensure the process of continual quality improvement. The External Opinion Processing Division is mainly responsible for dealing with user complaints and feedback, together with the related departments, and carrying out user satisfaction surveys. The Quality Assurance Division of each examination department, established at the beginning of 2015, is responsible for monitoring and managing the process quality to continuously improve the quality of examination together with other quality management officers in the department, and is also responsible for providing quality assurance, examination guidance and training for Patent Examination Cooperation Centers (PECC<u>s</u>) in the same technical field.

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.

(a) Importance of meeting treaty and regulatory requirements is communicated to staff in the CNIPA through training, seminars, and so on. For example, the Legal Affairs Department translates and distributes Compilation of the PCT Legal Instruments to examiners; Patent Examination Administration Department has completed the revision of practical work manual; the Quality Evaluation Division reports identified deficiencies to all the examiners; the Personnel & Education Department provides an advanced program tailored to the experienced examiners who are expected to be PCT examiners to help them learn and understand the treaty and regulatory requirements. Besides, various PCT related seminars or lectures are frequently held to ensure the PCT examiners fully aware of examination and quality criteria.

(b) A website which contains the information about QMS is established in the CNIPA on intranet and is available for all the examiners. Moreover, <u>various means</u>-seminars introducing the implementation of the QMS<u>_-including seminars, videos, training session</u>, are <u>heldused</u> in the CNIPA to help examiners understand the importance of complying with the 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 by the relevant staff at the respective Authority.

(a) Quality management related meetings are organized to review the QMS, so as to identify deficiencies and take corresponding improvement measures.

(b) &(c) The CNIPA regularly reviews quality objectives to ensure that the quality objectives are understood by the examiners and the relevant staff.

21.09 Indicate whether top management or delegated officers of the Authority perform an internal review of the QMS in accordance with paragraphs 21.27-21.30:

- (a) at least once per year (cf. paragraph 21.27);
- (b) in accordance with the minimum scope of such reviews as set out in Section 9, namely:

to determine the extent to which the QMS is based on Chapter 21 (cf. paragraphs 21.27, 21.29(i));

to determine the extent to which Search and Examination work complies with PCT Guidelines (cf. paragraphs 21.27, 21.29(i));

- (c) in an objective and transparent way (cf. paragraph 21.27);
- (d) using input including information according to paragraphs 21.29 (ii)-(vi);
- (e) recording the results (cf. paragraph 21.30).

(a-b) Every six months, a quality management seminar is held for all the Director Generals in the CNIPA to determine the extent to which Search and Examination work complies with PCT Guidelines.

Internal review is carried out according to the data provided by the Quality Evaluation Division, the Quality Evaluation Working Group and Preliminary Examination & Flow Management Department. The extent to which Search and Examination work complies with PCT Guidelines

is assessed in three aspects, that is, correct conclusion, consistent practice and examination periods. The Deputy Commissioner in charge concludes and instructs the quality improvement plan for the next term on the seminar.

(c) Main problems identified by the Quality Evaluation Division and the Quality Evaluation Working Group are sent to and discussed with corresponding examination departments to make sure the problems will be solved properly and timely.

(d) Information according to paragraphs 21.29(ii)-(vi) has been used in the internal review in the CNIPA.

(e) Results of internal review are recorded in formal documents.

21.10 Indicate whether top management of the Authority promote practices to ensure that risks and opportunities that can affect its QMS and the conformity of international search and examination are addressed.

Outcomes of quality_Top CNIPA management related meetings are reported to the Deputy Commissioner in charge to reviews the QMS regularly. The Deputy Commissioner in charge authorizes and promotes practices to ensure the risks and opportunities that can affect the QMS and the conformity of international search and examination are addressed.

2. RISK-BASED PRACTICES

21.11 Explanatory note: Each Authority should establish its own risk-based practices to enable the Authority to determine factors that could cause operational processes and its quality management system to deviate from requirements or planned results, to put in pace preventive controls to minimize negative effects, and to make use of opportunities as they arise.

21.12 Explanatory note: It is open to each Authority to set up its own arrangements to determine the effect of uncertainty on objectives. Paragraph 21.13 provides a guide to the basic components of risk-based practices as an element of QMS. There is no requirement for formal methods of risk management or a documented risk management process.

(Note: These points are informative. No response is required by the template to paragraphs 21.11 and 21.12).

21.13 Arrangements for establishing risk-based practices

Provide information on the arrangements that your Authority has made to:

(i) (a) understand issues that affect its ability to achieve intended results of the QMS, and

(b) understand the needs and expectations of interested parties;

(ii) identify risks and opportunities related to the performance of the QMS as a basis for planning;

- (iii) plan and implement actions to address risks and opportunities;
- (iv) check the effectiveness of the actions taken; and
- (v) continuously update risks and opportunities.

21.14 Explanatory note: All processes of the QMS present differing levels of risk in terms of the Authority's ability to meet its objectives, and the effects of uncertainty are not the same for all Authorities. Each Authority is responsible for the actions it decides to take to address risks and opportunities.

(Note: This point is informative. No response is required by the template to paragraph 21.14).

(i-v) The CNIPA convenes quality management related meetings to find out issues affecting the CNIPA's ability to achieve intended results of the QMS, and identifies risks and opportunities related to the performance of the QMS, and quality management meetings are platforms to discuss potential issues affecting the CNIPA's ability to achieve intended results of the QMS if needed. The CNIPA communicates with interested parties through various channels to

understand their needs and expectations, such as receiving user feedback, conducting user satisfaction surveys and holding meetings with users.

The CNIPA considers quality improvement plan for the next term based on risks and opportunities related to the performance of the QMS. The CNIPA also solves the issues related to performance of quality by PDCA cycle system.

3. **RESOURCES**

21.15 Explanatory note: The granting of ISA/IPEA 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 below, should provide this assurance.

Human resources:

(i) Provide information about the infrastructure in place to ensure that a quantity of staff:

sufficient to deal with the inflow of work;

which maintains the technical qualifications to search and examine in the required technical fields; and

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.

(ii) Describe the infrastructure in place to ensure that a quantity of appropriately trained/skilled administrative staff is maintained and adapted to changes in workload:

at a level to support the technically qualified staff and facilitate the search and examination process, and

for the documentation of records.

(i) The quantity of PCT examiners needed is calculated at the beginning of every year, according to the estimated amount of PCT applications, to ensure the PCT examiners in the CNIPA are sufficient for the increasing workload.

All the candidates have to pass a technical qualification certification held by The Personnel & Education Department to be substantive examiners, whose professional knowledge covers all technical fields. Only the skilled ones with at least 3 years experience in substantive examination are expected to be PCT examiners, who have to pass the PCT qualification certification.

PCT examiners are proficient at English. Some are also good at other foreign languages, such as French, German, etc. Moreover, the Personnel & Education Department provides foreign language training for examiners. The translation Division under the Search Advice Center is capable of providing translations in multiple languages, such as German, French, and Japanese etc, which are sufficient to cover the languages involved in the minimum documentation referred to in Rule 34.

(ii) The Preliminary Examination & Flow Management Department is in charge of handling S&E requests, sending reports to WIPO and other related processes, which provides technically qualified staff and facilitates the processing of S&E. Quantity of staff in Preliminary Examination & Flow Management Department is calculated according to the anticipated requests, which ensures adequate staff dealing with the administrative process. Besides, the administrative staffs in the Legal Affairs Department and Patent Examination Administration Department are also fully sufficient and competent to support PCT examiners well.

Material resources:

(iii) Describe the infrastructure in place to ensure that appropriate equipment and facilities such as IT hardware and software to support the search and examination process are provided and maintained;

(iv) Describe the infrastructure in place to ensure that 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.

(v) Describe how instructions:

to help staff understand and adhere to the quality criteria and standards; and;

to follow work procedures accurately and consistently

are documented, provided to staff, kept up-to-date and adapted where necessary.

(iii) The Automation Department in the CNIPA is responsible for maintaining and updating all inhouse computer hardware, software, networks and databases. Each staff in the CNIPA has a desktop connected to the Intranet, and each desktop is installed with the software allowing for the access to the search databases and the electronic processing system for patent applications. Furthermore, each examiner is also equipped with a notebook PC to access the Internet to consult external databases and resources directly.

(iv) The Documentation Department in the CNIPA is in charge of collecting and maintaining patent and non-patent documentation databases. The CNIPA possesses or has the access to the comprehensive documentation referred in Rule 34 in electronic form. Examiners can use continuously updated internal search system to search patent documents and also can use the search system and various commercial databases to access non-patent literature. On September 30, 2011, the CNIPA's proposal on incorporating Chinese patent documentation in PCT minimum documentation was passed.

(v) The quality <u>evaluation</u> standard for S&E work is published and distributed in the CNIPA. Each examiner can get it on intranet. A lot of seminars have been held to explain this standard, with materials dispensed. Collections of examples are also published to help examiners understand it better. Problems and deficiencies identified during checking are communicated with examiners, which also serve as explaining and training for the quality standard. Besides, courses introducing the QMS have been added to the enrolling training to introduce the quality criteria and standards.

The Patent Examination Administration Department issued a practical work manual in July 2007 and revised it in March 2012 and May 2020, to further specify the search and examination standards. This work manual not only assorts and integrates all the PCT legislations and guidelines, but also illustrates the PCT search and examination procedures via various examples under different situations, which contribute to instructions for examiners to follow work procedures accurately and consistently.

Training resources:

(vi) Describe the training and development infrastructure and program which ensures that all staff involved in the search and examination process:

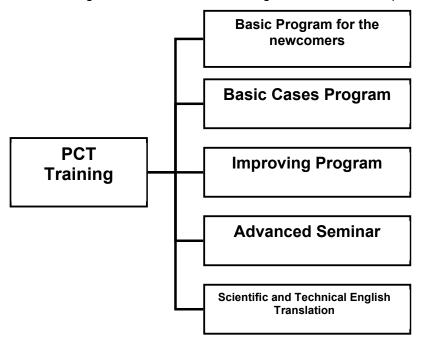
acquire and maintain the necessary experience and skills; and

are fully aware of the importance of complying with the quality criteria and standards.

Initial Report on Quality Management Systems by <u>Error! Reference source not</u> <u>found.Error! Reference source not found.</u> Month xx, 2012

(vi) PCT training in the CNIPA covers three phases, entry training for substantive examiners, <u>on-the-job</u> training, and improving training. The entry training introduces main procedure of PCT international application, international phase examination of PCT international application, and national phase examination of PCT international application. TheOn-the-job training focuses on looking back the main procedure of PCT international application and national phase examination of PCT international application.

The improving training designed for the PCT examiners consists of basic program for the newcomers, basic cases program, improving program, and advanced seminar, scientific and technical English translation. The following chart shows this improving training in detail.



In addition, many foreign language courses are run annually within the CNIPA, involving English, Japanese, German, French, etc.

As for the training about the awareness of the importance of complying with the quality criteria and standards, see 21.07 (a).

Oversight over resources:

(vii) Describe the system in place for continuously monitoring and identifying the resources required:

to deal with demand; and

comply with the quality standards for search and examination.

(vii) A report mechanism is running in the CNIPA. Any department, which finds problems with the resources mentioned above, can report to the corresponding departments which are in charge of the resource. After exchanging information among these departments, the problems will be settled.

4. MANAGEMENT OF ADMINISTRATIVE WORKLOAD

21.16 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:

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

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

(i) An electronic flow management system (CEPCT) was launched on March 31, 2014. When an original international application arrives at the Preliminary Examination & Flow Management Department, the formality examiners shall work on the formality examination, data-entry of the bibliography information and initial classification in the <u>L-sSystem</u>. Then the processed record copies and search copies are handed over to the International Bureau and PCT examiners with corresponding technical fields via <u>CEPCT-I-system</u> electronically. The deadlines for all these actions are automatically calculated according to the initial entry data. Both <u>CEPCT-I-sSystem</u> and his/her supervisors will remind the formality examiner sometime before the deadline.

(ii) See 21.15(ii)

5. QUALITY ASSURANCE

21.17 In accordance with the Guidelines, the following are required quality assurance measures for timely issue of search and examination reports of a high quality. Indicate how the following are implemented, including the use of any checklists to verify reports before their issue or for monitoring the quality as part of a post-issue review process:

(i) An internal quality assurance system for self-assessment, involving verification, validation and monitoring of searches and examination work:

for compliance with these Search and Examination Guidelines;

for channeling feedback to staff.

(ii) 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.

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

(i) An internal quality assurance system is running in the CNIPA both in process and product. In process, deficiencies in the International Search Reports (ISRs), the Written Opinions of the International Searching Authority and the International Preliminary Examination Reports (IPERs) are identified and corresponding actions will be taken before ISRs and IPERs are sent to WIPO, which assures the correctness.

Time limitation of search and examination reports is automatically monitored via <u>I-sSystem</u> <u>CEPCT</u>, which sends warning message to examiners sometime before the deadline. His or her supervisors will remind the examiner to finish the reports in time.

Rechecking is performed both individually and collectively. All the ISRs, written opinions and IPERs are now conducted by a two-person team consisting of a primary examiner and a reviewing member. After the main search and examination is completed by the primary examiner, the reviewing member, serving as a second pair of eyes, shall review the case comprehensively. A reviewing opinion then shall be made and kept in file, and fed back to the primary examiner. The primary examiner shall amend or supplement his/her action if necessary, or otherwise give an explanation to the reviewing opinion. <u>before it is sent to the Preliminary</u>

Examination & Flow Management Department where all these ISRs, written opinions and IPERs are collected and formally checked again in an all-round manner before they are transmitted to the IB and applicants as well. Furthermore, all the defects discovered are recorded and reported to the director of the Examination Department per month. Encouragement and reminder measures may be taken accordingly within the department.

Substantive inspection reviews during the process is carried out at the division and department levels. Namely, quality management officers in the Examination Divisions and Departments randomly check some cases per month and carefully observe substantial issues, such as search strategy, evaluation of novelty, inventive step, etc. The primary examiner shall amend or supplement his/her action if necessary before sending it to the Preliminary Examination & Flow Management Department.

In the product evaluation phase, evaluation is carried out in the department and office levels. Quality management officers in each examination department choose cases randomly to check the extent to which these cases comply with the Search and Examination Guidelines, and trainings are held on problems identified by the quality officers, so as to ensure the PCT examiners fully understand the requirements of the Search and Examination Guidelines. The Quality Evaluation Division and the Quality Evaluation Working Group are composed of experienced examiners selected from each Examination Department. The Quality Evaluation Division and the Quality Evaluation Working Group check random samples every month to see the extent to which these samples comply with the Search and Examination Guidelines. Main problems identified by the Quality Evaluation Division and the Quality Evaluation Working Group are sent to and discussed with corresponding examination departments to make sure the problems will be solved properly and timely.

(ii)(iii) Quality management officers in each examination department record the identified problems, and problems with high frequency are collected and analyzed to find out the underlying causes thereof, which will be used as the basis for subsequent training.

Every six months, the quality assurance results are reported to Deputy Commissioner in charge and all the Director Generals. A quality management seminar with Deputy Commissioner in charge and all the Director Generals joining follows to conclude the assessing results and quality plan for the next term.

6. COMMUNICATION

Inter-Authority communication:

21.18 Explanatory note: Each Authority should provide for effective communication with other Authorities.

(Note: This point is informative. No response is required by the template to paragraph 21.18)

21.19 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.

(a-c) The quality contact persons designated in the CNIPA are Zhou Qing, Consultant of the Quality Management Division, and Bian Yuhan, Principle Staff MemberDeputy Consultant of

Initial Report on Quality Management Systems by <u>Error! Reference source not found.Error!</u> <u>Reference source not found.[INSERT NAME OF OFFICE]</u> DATE page 15

International Cooperation Division, who can be contacted by e-mail, zhouqing@cnipa.gov.cn, bianyuhan@cnipa.gov.cn.

Communication and guidance to users:

21.20 Describe the system in place for monitoring and using customer feedback including at least the following elements:

(i) An appropriate system for

handling complaints and making corrections;

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, giving details of where it is to be found e.g. link to Authority's web site, guidance literature.

Indicate where and how the Authority makes its quality objectives publicly available for the users.

(i) The CNIPA has established Examination Quality Feedback Platform. Logging in the Examination Quality Feedback Platform, anyone who may be applicants/attorneys, the public, the IB, DOs, EOs or WIPO, can complain about examination quality regarding the whole examination process. The CNIPA will deal with the complaints within the specified time limit and offer the solutions to users.

(ii) In order to generally understand opinions from users, the CNIPA has commissioned professional survey institute to conduct a user satisfaction survey on examination quality annually since 2008. The survey result suggests that customers have good opinion of the PCT search and preliminary examination report and service. Meanwhile, we also learn the weaknesses and disadvantages, as well as improving suggestions for our PCT products from our users and customers.

(iii) Guidance to users on the search and examination process is accessed on the CNIPA's website (http://www.cnipa.gov.cn/col/col45/index.html), which includes basic PCT related knowledge, PCT forms and news, PCT applying programs and FAQ. Training seminars, especially WIPO national roving seminars on PCT cooperated with the WIPO are frequently run all over the country.

The quality objectives are often stated at the meetings with users.

21.21 Communication with WIPO and designated and elected Offices:

Describe how the Authority provides for effective communication with the International Bureau and designated and elected offices. In particular describe how the Authority ensures that feedback is promptly evaluated and addressed.

Several departments, including International Cooperation Department and Patent Examination Administration Department are designated to communicate with WIPO, including attending WIPO meetings, giving feedback to WIPO on time.

7. DOCUMENTATION

21.22 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 by documenting the procedures and processes affecting the quality of work as a reference for staff and management at the Authority (see paragraph 21.23).

(Note: This point is informative. No response is required by the template to paragraph 21.22)

21.23 The material that makes up the reference for staff and management at the Authority serves to document the procedures and processes affecting the quality of work, such as classification, search, examination and related administrative work. In particular, the reference indicates where to find instructions on the procedures to be followed.

For the purposes of this report indicate:

- (a) the documents making up the reference that have been prepared and distributed;
- (b) the media on which they are supported (e.g. Internal Publication, Internet, Intranet); and
- (c) document control measures taken e.g. version numbering, access to latest version.

(a) Quality Assurance Manual have been prepared and distributed.

- (b) The available documents are published on the Intranet, Internet or paper.
- (c) The available documents are numbered in different versions.
- 21.24 Indicate whether the material making up the reference of quality procedures and processes include the following:

(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.

(i-vi) The Quality Assurance Manual of the CNIPA includes the items shown in (i-vi) above.

21.25 Indicate which types of records the Authority maintains, such as:
(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 products, 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 8.

(i)(ii) Relevant records have been established in the CNIPA.

(iii) Records of training, skills and experience of personnel are kept and maintained by the Personnel & Education Department.

(iv) Evidence of conformity of processes, resulting products and services in terms of quality standards are recorded in the quality <u>evaluation</u> reports every six months.

(v) Records of results of reviews of requirements relating to products are maintained.

(vi,vii,ix-xii) These are recorded by the CEPCT I-sSystem and maintained in the CNIPA.

(viii) Records of QMS audits have been established, such as minutes of quality management related meetings and summary reports on the QMS.

8. SEARCH PROCESS DOCUMENTATION

| 21.26 For internal purposes the Authority should document its search process. | | | | | | | |
|---|---|--|--|--|--|--|--|
| The Authority should indicate | | | | | | | |
| <i>(a)</i> w |) which of the following are included in this record: | | | | | | |
| (i) | i) the databases consulted (patent and non patent literature); | | | | | | |
| (i | ii) the keywords, combinations of words and truncations used; | | | | | | |
| (i | 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. | | | | | | |
| of the s | (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) w | which special cases are documented and whether records are kept denoting any: | | | | | | |
| () | vi) limitation of search and its justification | | | | | | |
| () | vii) lack of clarity of the claims; and | | | | | | |
| () | viii) lack of unity. | | | | | | |

(a) (i-v) Search process record includes the databases consulted (patent and non patent literature), 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 list of all search statements used in the databases consulted.

(b) Other relevant information are included in this record, such as details of special relevance to internet searching, synonym databases etc.

(c) Special cases are documented and records are kept denoting limitation of search and its justification, lack of clarity of the claims, and lack of unity.

9. INTERNAL REVIEW

21.27 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.

21.28-21.30 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.

Internal review in the CNIPA has been implemented semiannually since 2008, which is convened by Deputy Commissioner in charge, with all the Director Generals from Examination Departments joining. Data evaluating the conformity of S&E work with PCT Guidelines these six

months is published and deficiencies identified by the Quality Evaluation Division and the Quality Evaluation Working Group are discussed at the seminar.

Deputy Commissioner in charge concludes and instructs the quality improvement plan for the next term. Due to great efforts in these years, the quality management system is gradually improving and deficiencies identified are more and more critical to the PCT examination, which perfects the internal review in the CNIPA.

10. ARRANGEMENTS FOR AUTHORITIES TO REPORT TO THE MIA

21.31 There are two stages in the reporting arrangements outlined in Chapter 21: the initial report called for by paragraph 21.31(a), and annual reports in accordance with paragraph 21.31(b). Authorities should submit each report in the form of a full report, making the differences from the previous year's report clear, for example using "track changes" or other form of highlighting.

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