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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 State Intellectual Property Organization, China

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 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

The State Intellectual Property Office (SIPO) of China 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 Evaluation System and quality management measures, the great performance concerning time limit control and correctness of ISR and IPER has been achieved.

1. LEADERSHIP AND POLICY

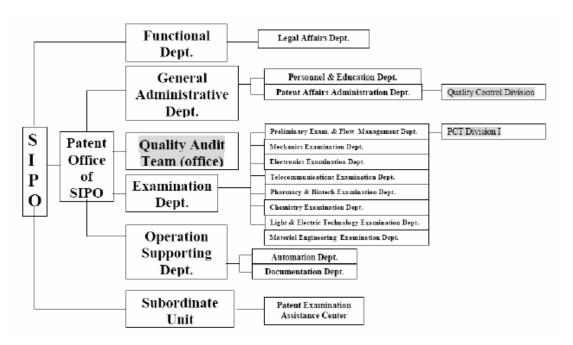
21.04 Confirm that the following are clearly documented, and that this documentation is available internally:

- (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.
- (a) The quality policy has not been established in SIPO.
- (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. Quality policy is under development.

The Quality Control Division under the Patent Affairs Administration Department is responsible for implementing and maintaining the QMS, and defining the quality standards for all our products and services. The Quality Audit Teams at office tier, reporting directly to the deputy commissioner of SIPO, is in charge of auditing the compliance of products with these quality standards.

Quality officer in each examination department monitors and controls process quality for continuous improvement. Automation Department and Documentation Department provides 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.

Chapter 21 requirement			Extent of compliance		
			full	part	no
21.04	(a)	Quality policy available			✓
	(b)	Identified roles and names for QMS responsibility	✓		
	(c)	Organisational 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			✓
	(c)	Communication of quality objectives throughout the Authority			✓
21.09	(a)	Performance of a yearly internal review of the QMS in/to	✓		
	(b)	(i) determine the extent to which the QMS in based on Chapter 21			√
		(ii) determine the extent to which S&E complies with PCT Guidelines	✓		
	(c)	an objective and transparent way	√		
	(d)	using input incl. information according paragraph 21.27			✓
	(e)	recording the results	✓		
21.10		Assurance to monitor and adapt to actual workload	✓		
21.11	(a)	Infrastructure in place to ensure that a quantity of staff	√		
		(i) sufficient to deal with the inflow of work	√		
		(ii) which maintains tech. qualifications to S&E in all technical fields	✓		
		(iii) which maintains the language facilities to understand languages according to Rule 34	✓		
	(b)	Infrastructure to provide a quantity of skilled administrative staff	√		
		(i) at a level to support the technically qualified staff	✓		

Chapter 21 requirement			Extent of compliance		
			full	part	no
		(ii) for the documentation records			✓
21.12	(a)	(i) Ensuring appropriate equipment to carry out S&E	✓		
		(ii) Ensuring documentation accord. to Rule 34	✓		
	(b)	(i) Instructions to help staff understand and act accord. the quality criteria and standards	√		
		(ii) Instructions to follow work procedures accurately and they are kept up-to-date.	√		
21.13		(i) L&D program to ensure and maintain necessary skills in S&E	✓		
		(ii) L&D program to ensure awareness of staff to comply with the quality criteria and standards.	✓		
21.14	(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		✓	
21.15	(a)	Control mechanisms to ensure timely issue of S&E reports	√		
	(b)	Control mech. regarding fluctuations in demand and backlog	✓		
21.16	(a)	Internal quality assurance system for self assessment	✓		
		(i) for compliance with S&E Guidelines	✓		
		(ii) for channelling feedback to staff	✓		
	(b)	A system for measurement of data and reporting for continuous improvement	√		
	(c)	System for verifying the effectiveness of actions taken to correct deficient S&E work	√		
21.17	(a)	Contact person helping identify best practice between Authorities	√		
	(b)	Contact person fostering continual improvement	✓		
	(c)	Contact person providing for effective comm. with other Authorities for feedback and evaluation	✓		
21.18	(a)	(i) Appropriate system for handling complaints	✓		
		(ii) Appropriate system for taking preventive/corrective actions	✓		
		(iii) Appropriate system for offering feedback to users	✓		
	(b)	(i) A procedure for monitoring user satisfaction & perception	✓		
		(ii) A procedure for ensuring their legitimate needs and expectations are met	✓		

Chapter 21 requirement			Extent of compliance		
			full	part	no
	(c)	Clear and concise guidance on the S&E process for the user	✓		
	(d)	Indication where and how the Authority makes its quality objectives publicly available	√		
21.19		Established comm. with WIPO and desig. + elected offices	√		
21.20		QMS of Authority clearly described (e.g. Quality Manual)		✓	
21.21	(a)	Documents making up the Quality Manual have been prepared and distributed		√	
	(b)	Media available to support the Quality Manual	✓		
	(c)	Document control measures are taken	✓		
21.22	(a)	Quality policy of the Authority and commitment to QMS			✓
	(b)	Scope of QMS			✓
	(c)	Organizational structure and responsibilities	✓		
	(d)	the documented processes are carried out in the Authority	✓		
	(e)	Resources available to carry out processes			✓
	(f)	a description of the interaction between the processes and the procedures of the QMS.			√
21.23	(a)	Records which documents are kept and where they are kept			✓
	(b)	Records of results of management review			✓
	(c)	Records about training, skills and experience of staff	✓		
	(d)	Evidence of conformity of processes	✓		
	(e)	Results of reviews of requirements relating to products	✓		
	(f)	Records of the S&E process carried out on each application	✓		
	(g)	Record of data allowing individual work to be tracked	✓		
	(h)	Record of QMS audits			✓
	(i)	Records on actions taken re. non-conforming products	✓		
	(j)	Records on actions taken re. corrective actions	✓		
	(k)	Records on actions taken re. preventive actions	✓		
	(I)	Records referring to search process documentation	✓		
21.24	(a)	(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	✓		

Chapter 21 requirement			Extent of compliance		
			full	part	no
		(iv) Recording of classes and combinations thereof consulted during search	✓		
	(b)	Records about other information relevant to the search	✓		
	(c)	(i) Records about limitation of search and its justification	✓		
		(ii) Records about lack of clarity of the claims	✓		
		(iii) Records about lack of unity	✓		
21.25		Report on its own internal review processes	✓		
21.26- 21.28		Additional information on further inputs to its internal reviews			✓
21.29		Initial report called for by paragraph 21.19	✓		

- 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 Control Division under the Patent Affairs Administration Department is responsible for implementing and maintaining the QMS, to ensure the effectiveness of the QMS.
- (b) The Quality Control Division under the Patent Affairs Administration Department is responsible for defining the quality standards for all our products and services and establishing effective measures to ensure the process of continual improvement progresses. Quality officer in each examination department monitors and controls process quality for continuous improvement.
- 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 SIPO through training, seminars, and so on. For example, the Legal Affairs Department translates and distributes Compilation of the PCT Legal Instruments to examiners; Patent Affair Administration Department is getting down to the revision of practical work manual; Quality Audit Team at the office tier 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, helping 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 all the information about QMS is established in SIPO on intranet and available for all the examiners. Moreover, seminars introducing the implementation of the QMS are held in SIPO 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 throughout the respective Authority.
- (a) Management reviews have not been established in SIPO.
- (b)(c) Quality objectives haven't been set in SIPO.
- 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).
- (a) Every six months, a quality control seminar is held for all the directors in SIPO to determine the extent to which Search and Examination work complies with PCT Guidelines. The latest seminar was in March 2010.

(b)

- (i) Internal review in SIPO does not include determining the extent to which QMS is based on Chapter 21.
- (ii) Internal review is carried out according to the data provided by Quality Audit Team at the office tier and Preliminary Examination & Flow Management Department. The extent to which Search and Examination work complies with PCT Guidelines is assessed through correctness, timeliness and consistency. The Deputy Commissioner in charge concludes and instructs the quality improvement plan for the next term on the seminar.
- (c) All the problems identified by Quality Audit Team at the office tier are sent to and discussed with each examination department to make sure the data provided to the seminar is agreed on between both of them. And results of assessment are also sent to examination departments.
- (d) Information according to paragraphs 21.27(b)-(f) has not been used in the internal review in SIPO.
- (e) Results of internal review are recorded in a formal document.

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.

(a)

- (i) The Quality Control Division calculates the quantity of PCT examiners needed at the beginning of every year, according to the estimated amount of PCT application, to ensure the PCT examiners in SIPO is sufficient for the increasing workload.
- (ii) All the candidates have to pass a technical qualification test hold by The Personnel & Education Department and Examination Departments to be substantive examiners, whose professional knowledge covers all 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 another qualification test.
- (iii) PCT examiners are proficient at English. Some are also good at another foreign language, such as French, German, etc. Moreover, Personnel & Education Department provides foreign language training for examiners. Translation Division under the Search Advice Center provides translations for plenty of languages, such as German, French, and Japanese etc, which is sufficient for languages in the minimum documentation referred to in Rule 34.

(b)

- (i) Preliminary Exam & Flow Management Department is in charge of handling S&E requests, sending reports to WIPO and other related processes, which supports the technically qualified staff and facilitates the S&E processes. Quantity of staff in Preliminary Exam & Flow Management Department is calculated according to the anticipated requests, which ensures adequate staff dealing with the administrative process. Besides, the administrative staff in the Legal Affairs Department, and Patent Affairs Administration Department (especially the Quality Control Division) is also fully sufficient and competent to support PCT examiners well.
- (ii) The administrative staffs don't maintain 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.

(a)

- (i) The Automation Department in SIPO is responsible for maintaining and updating all in-house computer hardware, software, networks and database. Each staff in SIPO 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.
- (ii) The Documentation Department in SIPO is in charge of collecting and maintaining non-patent documentation databases. SIPO possesses or has the access to the comprehensive documentation referred to in Rule 34 in electronic form (see Annex 2). SIPO has possessed 3,800,000 full text patent documents since September 2010. Besides, more than 6900 Chinese periodicals, 10,000 periodicals in foreign languages, 2 million Chinese dissertations and 1 million Chinese books are available on intranet.

(b)

- (i) The quality standard for S&E work is published and distributed in SIPO. Each examiner can get it on intranet. A lot of seminars have been hold 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 serves as explaining and training of quality standard. Besides, courses introducing the QMS have been added to the enrolling training to introduce the quality criteria and standards.
- (ii)The Patent Affairs Administration Department issued a practical work manual in July 2007 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. In order to keep the manual up-to-date, Patent Affair Administration Department is getting down to the revision of practical work manual.

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.

(i) PCT training in SIPO covers three phases, entry training for substantive examiners, job training, and improving training. The entry training introduces main procedure in PCT international application, PCT international application international phase examination, and PCT international application national phase examination. The job training focuses on looking back on the main procedure in PCT international application and PCT international application national phase examination.

The improving training designed for the PCT examiners consists of basic program for the newcomers, basic cases program, improving program, advanced seminar, translation of scientific and technical English. Annex 3 shows this improving training in detail.

In addition, many foreign language courses are running annually within SIPO, concerning English, Japanese, German, French, etc.

(ii) See 21.07 (a).

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

(a)&(b)

A report mechanism is running in SIPO. 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..

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.

(a)

An electronic flow management system EPCT was launched on Jan 01, 2007, which greatly improves workflow efficiency. 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 system. Then the processed record copies and search copies are handed over to the International Bureau and PCT examiners with corresponding technical fields via EPCT electronically. The deadlines for all these actions are automatically calculated according to the initial entry data. Both EPCT and his/her supervisors will remind the formality examiner some time before the deadline.

(b) See 21.11(b).

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.

(a)

(i) (ii) An internal quality assurance system is running in SIPO 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 sent to WIPO, which assures the correctness and timeliness of process.

Time limitation of search and examination reports is automatically monitored via EPCT, which sends warning message to examiners sometime before the deadline. His or her supervisors will reminds 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 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 before it is sent to the Preliminary 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 punishment measures may be taken accordingly within the department.

Substantive inspection during the procedure is carried out at the division and department tiers. Namely, directors 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, Quality Audit Team at the office tier, which is headed by a Director General from one of the Examination Departments and composed of experienced examiners selected from each Examination Department. The Quality Audit Team checks random samples every month to see the extent to which these samples comply with the Search and Examination Guidelines.

By the end of every month, a quality record with identified problems is distributed to each Examination Department. Every two months, the team publishes a quality cases collection in the intranet which includes an outline of the relevant cases and identified problems, the detailed

analysis of the causes for the problems, and a specification of relevant examination and quality standards.

(b)(c)

PCT Quality Evaluation System has been launched since 2008, which aims at assessing the quality of each Examination Department and verifying the effectiveness of actions taken by timeliness, correctness and consistency. The correctness data for evaluation is provided by the Quality Audit Team. The timeliness and consistency data are taken out of the EPCT system. Every six months, the assessing results are published to Deputy Commissioner in charge and all the directors. A quality control seminar with Deputy Commissioner in charge and all the directors joining follows to conclude the assessing results and plan for the next term.

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.

(a-c) The quality contact persons designated in SIPO are Han Aipeng who is the head of Quality Control Division and Staff Member in Chief Xialei, who can be contacted by e-mail hanaipeng@sipo.gov.cn, xialei@sipo.gov.cn.

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.

(a)

(i-iii) SIPO has established External Feedback Mechanism and Service Hot line to receive complaints. The All-China Patent Agency Association(APAA) is delegated to implement the mechanism. External feedback resources include applicants/attorneys, the public, the IB, DOs, EOs and WIPO. Service Hot line is available day and night. All the complaints are divided into two kinds, those relevant to problems in agreement on and the others still in dispute in SIPO. For

the first kind, feedback will be provided to complainants as soon as possible, including explaining or correction. For the second kind, an Dispute Settlement Mechanism supported by Standard Constitution, Quality Control, Training, and Studies will be started to discuss the problems and take corresponding action. Effectiveness of actions or corrections is still verified through the External Feedback Mechanism.

(b)

- (i)&(ii)In order to learn opinions from the users generally, SIPO has commissioned professional survey institute to make a user satisfaction survey on examination quality in 2009 for the first time, which is a significant attempt. The survey result suggests that costumers have a good opinion of the PCT search and preliminary examination report and service. Meanwhile, we also learn the weakness and disadvantages, as well as improving suggestions for our PCT products from our users and costumers.
- (c) Guidance to the users on the search and examination process is accessed on SIPO's website (www.sipo.gov.cn/sipo/pct), which includes basic PCT related knowledge, PCT forms and news, PCT applying program and FAQ. Training seminars, especially WIPO national roving seminars on PCT cooperated with the WIPO are frequently run all over the country.
- (d) The instruction of quality objectives are not available for users now.
- 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

We have the honors of getting the abstract-translating quality feedback report quarterly from WIPO in 2009. The report concerns about specific grammar, mistranslation, terminology mistakes made in abstract submitted by SIPO. It is a very good and helpful abstract-drafting handbook, from which PCT examiners benefit a lot and are expect to decrease and avoid translating mistakes step by step. A person at Quality Control Division is specially designated to receive and analyze the reports from WIPO. All the results will be sent to the deputy commissioner and all the PCT examiners.

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.
- (a) Parts of Quality Manual have been prepared and distributed. The others are under development.

- (b) The available documents are published on intranet, internet or paper.
- (c) The available documents are numbered in different versions.
- 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.

(a)(b)

The quality policy has not been established in SIPO. The scope of the QMS hasn't been documented.

(c)

Organizational structure and responsibilities of each department are documented both on paper and electronically.

(d)

The Patent Affairs Administration Department issued a practical work manual in July 2007 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, such as receipt of incoming applications, classification, distribution, search, examination, publication processes etc.

(e)(f)

Documents of resources and interaction between processes and procedures are under development.

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
 - search process documentation as set out in Section 7.

(a)(b)

These records haven't been established in SIPO.

(c)

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

(d)

Evidence of conformity of processes, resulting products and services in terms of quality standards are recorded in the quality assessment reports every six months.

(e)

Records of results of reviews of requirements relating to products are maintained.

(f, g, i-l)

These are recorded by the EPCT system and maintained in SIPO.

(h)

Records of QMS audits haven't been established.

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.

(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 listing of all search statements used in the databases consulted.

(b)

Other relevant information is 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.

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

Internal review in SIPO has been implemented semiannually since 2008, which is convened by Deputy Commissioner in charge, with all the Directors from Examination Departments joining. Data evaluating the conformity of S&E work with PCT Guidelines and deficiencies identified these six months by Quality Audit Team at office tier 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 Evaluation System is gradually improving and deficiencies identified are more and more critical to the PCT examination, which perfects the internal review in SIPO.

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. It will be supplemented annually by further reports in accordance with paragraph 21.30.

[End of document]