PATENT COOPERATION TREATY

Common Quality Framework for International Search and Preliminary Examination

Report Under Paragraph 21.17 of the PCT International Search and Preliminary Examination Guidelines

by: National Board of Patents and Registrations of

Finland

on: **22.12.2006**

Documents referred to in this report: Quality manual en.pdf QMS Process Chart PRH.pdf PAI org.pdf

Each Authority must provide information with respect to its Quality Management System (QMS) arranged under the main headings as set forth in this template. The descriptions in this template below each main heading 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.

This template is to be used for a main report under paragraph 21.17 of the PCT International Search and Preliminary Examination Guidelines. Updating reports may thereafter usually be presented in abbreviated format using template T21-18.

INTRODUCTION (PARAGRAPHS 21.01–21.02)

The Authority should provide general background information relevant to the quality management system (QMS). The following may be included, if applicable:

• Recognised normative reference or basis for quality management system besides Chapter 21, e.g. ISO 9000.

The National Board of Patents and Registrations of Finland (PRH) has established a quality management system which complies with the requirements of ISO 9001:2000. Actually, our system was granted a quality certificate by Inspecta Certification on 23.11.2006.

• An organigram showing at least the organizational units responsible for implementation of the Authority's QMS. It could be referred to in the rest of the report, as necessary.

PAI_org.pdf

QUALITY MANAGEMENT SYSTEM (PARAGRAPHS 21.03–21.09)

Establishment and maintenance of QMS (Paragraph 21.03)

The Authority should show that it has established and is maintaining, or is establishing, a QMS which:

(a) sets out basic requirements regarding resources, administrative procedures, feedback and communication channels required to underpin search and examination (S&E);

PRH has a quality management system which meets all requirements of ISO 9001:2000. The PRH QMS is described and maintained in electronic form. The QMS is described in our quality manual with links to relevant documentation.

(b) incorporates a quality assurance scheme for monitoring compliance with these basic requirements and with PCT/GL/ISPE.

The PRH PCT search and examination procedure is harmonised according to the PCT Guidelines. We have established a Quality Assurance System, which comprises crosschecks by second examiners and quality checks by heads of the technical divisions. The working group on PCT processes ensures that the PRH S&E process incorporates with the requirements of PCT/GL/ISPE.

resources - infrastructure (Paragraph 21.05)

Provide information about the infrastructure in place which ensures the following:

(a) Adequate quantity of search and examination (S&E) staff, including:

(i) means for matching the quantity of S&E staff to the inflow of work;

Staff recruitment is based on the workload in the various technical fields. The number of qualified examiners is about [1]110, which is a sufficient staff to deal with the inflow of work. PRH is still in the process of recruiting new examiners.

Statistics is collected for the number of applications, person-years, and productivity, and the future developments of these figures are estimated. Heads of the technical divisions give details about the technical fields where new examiners are needed. The Management evaluates the need of new recruitments continuously.

(ii) means for ensuring that recruited S&E staff have the necessary technical qualifications;

The minimum competence requirements have been specified. A higher university degree is the mandatory minimum requirement for examiners; however, the highest degree (Ph D) is preferable.

(iii) means for ensuring that S&E staff have language skills, or have access to supporting translation arrangements, as necessary to meet Rule 34.

Language skill requirements have also been specified in the minimum requirements, and PRH has a translator service for examiners. Also, examiner workstations include electronic dictionaries.

PRH staff has a very good command of the English language, and continuous training is organised in French and German, too. Besides[2] the official languages of Finland, Finnish and Swedish, all examiners understand other Nordic languages, and staff has sufficient knowledge of German and French. Several of our examiners have good skills in other European languages, e.g., [3]Russian.

(iv) Adequate quantity and skills of administrative staff to support S&E.

The number of administrative support staff is about 10, which is sufficient to support the technical staff. Administrative staff is thoroughly trained to undertake the formalities work associated with the PCT search and examination.

(c) Provision of appropriate equipment and facilities to support S&E.

PRH has a modern IT infrastructure with updated hardware and software. Helpdesk provides quick assistance to users. PRH has a full electronic working environment including an electronic filing system, a dossier system, and a legacy system for monitoring all relevant due dates. PCT EDI is used to communicate with WIPO.

(d) Provision of the minimum documentation supporting S&E, as referred to in Rule 34.

PRH has access to all documentation needed to meet the requirements set by Rule 34, and even more. Most of the documentation is available online. Every examiner has access to the EPOQUEnet system of the European Patent Office from her/his desktop. The examiners have access to non-patent literature databases in all technical areas. Additionally, the examiners have access to the Internet. The Patent Library and Advisory Services monitors changes in the information environment and provides the staff with updated online magazines, periodicals, and databases.

(e) Provision of up-to-date work manuals. These must include explanations of:

All examiners have access to the PCT Guidelines and PCT Regulations. The Patents and Innovations Line maintains a Patents Manual, which provides guidance to examiners on all aspects relating to search and examination, and on communication to applicants. The Manual has separate [4]sections for function as an ISA and as an IPEA. The Manual is available on the intranet and on PRH's website, and it is updated regularly.

(i)quality criteria and standards;

The Quality Manual includes the quality criteria and standards.

(ii) descriptions of work procedures;

Our work procedures are described in the Patent Manual.

(iii) instructions ensuring that the work procedures are adhered to.

We have implemented a two-examiner system and quality checks by heads of division in order to ensure adherence to the work procedures agreed on. PRH has an electronic examiner desktop solution to ensure the QA system.

(f) Provision of an effective training and development program for all staff involved in S&E, including means to ensure the acquisition and maintenance of the necessary experience, skills and familiarity with work manuals. [5]

Both the examiners and administrative staff take part in a comprehensive training and development program, which covers all stages of the search and examination procedure, in order to acquire and maintain the necessary competences and expertise. The training program includes special units in [6] the PCT search and examination process. Special attention is paid on the quality standards and criteria in the different stages of search and examination. The training is career-long. Targeted training is provided as the need arises. Workshops and seminars on various technical fields are held regularly.

(g) Continuously monitoring and identifying resources, other than staff, required to deal with demand and comply with quality standards for S&E.

The Management continuously monitors the resources required to deal with any quality demand. If necessary, IT solutions, e.g., are improved, new databases are acquired or a working group is established in order to solve the issue.

Administration - procedures (Paragraphs 21.06(a) and (b))

Provide information on those administrative procedures and control mechanisms which ensure the following:

(a) Timeliness of S&E and related functions, to quality standards in accordance with PCT/GL/ISPE.

The PCT unit and heads of divisions monitor all the relevant due dates.

(b) Coping with fluctuations in demand and backlog management.

The Management continuously monitors both fluctuations in demand and possible backlogs. If necessary, new staff is recruited, the distribution of workload is reorganised, and staff is asked to temporarily work overtime.

Quality Assurance Procedures (Paragraph 21.07)

Provide information on procedures which ensure that S&E reports of a quality standard in accordance with PCT/GL/ISPE are issued. In particular, provide information on:

(a) Activities related to verification, validation and monitoring; as carried out in order to assess compliance of S&E work with PCT/GL/ISPE.

The PCT Working Group is responsible that the PRH S&E working procedures meet all requirements of PCT/GL/ISPE. A QA system has been introduced to ensure that the requirements and standards are met. The system includes crosschecks and quality checks by a second examiner, quality checks by heads of technical divisions and random checks by the QA Group. Every year the QA Group assesses one randomly selected case of each examiner against the assessment criteria. Every case is assessed to one level of three level degrees. A QA report is communicated to the examiner, second examiner, and head of division. The QA Group reports to the Quality Management Group.

(b) Processes for measuring, recording, monitoring and analysing performance of the QMS to assess its conformity with the requirements of Chapter 21 and, if applicable, any other normative reference for the QMS.

Quality objectives are specified for both the timeliness of search reports and QA work.

The Quality Management Group (QMG) analyses and monitors the performance of the QMS and assesses its conformity with Chapter 21 and ISO 9001:2000. The Group consists of the quality manager, heads of technical divisions, head of PCT Section, and quality administrators.

Management reviews are regularly organised in order to assess the system's conformity with the requirements of ISO 9001:2000 and Chapter 21.

- (c) Activities related to verifying the effectiveness of actions taken to deal with deficiencies, including:
 - (i) those actions taken to eliminate, correct or authorise release of deficient S&E work which does not comply with the quality standards;
 - Our QA system including second examiners and checks by heads of technical divisions is in place for eliminating deficient S&E work.
 - (ii) those actions taken to eliminate the causes of deficient S&E work and prevent the deficiencies from recurring.

The QMG discusses and analyses the causes of deficient S&E work and decides on preventive actions.

The QMG and QA reports and customer feedback is forwarded to the meetings of technical divisions.

The Working Group on Training takes into account these reports when planning training.

The Patent Manual is updated when necessary.

The PCT Working Group continuously monitors the requirements set on S&E.

An internal initiative system has been introduced to encourage new improvement ideas.

(d) Activities ensuring the continuous improvement of established processes underpinning the issue of S&E reports.

A Working Group on S&E reporting has been established in order to develop reporting tools.

Feedback arrangements (Paragraph 21.08)

Give information on arrangements to:

- (a) Provide feedback to staff informing them of results of verification, validation and monitoring carried out in order to assess compliance of S&E work, so that:
 - (i) deficient S&E work is corrected;

Feedback is communicated to relevant people and necessary actions are taken.

(ii) corrective action, i.e. action necessary to prevent recurrence, is identified and implemented;

The QA Group prepares a report on each examined case, which is communicated to the relevant examiners and the head of division.

All feedback from users is communicated to examiners.

Staff meetings are organised if necessary.

(ii) best practice is identified, disseminated and adopted.

The QA Group makes recommendations for best practices. The QMG Group discusses and decides on the practices, taking into account all available information. Best practices are taken into account in training and drawing up guidelines.

(iii) Accommodate prompt feedback from WIPO, designated and elected offices; so that potential systemic issues, e.g. recurring deficiencies of S&E work, as identified by these bodies, are evaluated and addressed.

The feedback from WIPO is handled in the PCT Unit and in the PCT Working Group.

Communication, Guidance and Responses to Users (Paragraphs 21.06(c), 21.09)

Give information on arrangements to:

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

Staff is available for applicants by e-mail or phone.

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

A general helpdesk service is available for customers. The PCT Unit provides detailed guidance for applicants. Training courses are organised. Our web pages are continuously improved for better guidance and information.

- (c) Monitor and react to user needs and feedback, including:
 - (i) measuring user satisfaction and perception;

Customer satisfaction surveys are organised every year.

A customer panel with members from PRH and representatives from the most important customer groups meets regularly.

A customer meeting is organised once a year to discuss relevant issues.

(ii) handling complaints;

Complaints are handled in the QMG. If the QMG agrees on a complaint, necessary corrective measures are taken.

(iii) correcting deficiencies identified by users;

Deficiencies identified by users are discussed in the QMG. If QMG agrees with the user, necessary corrective measures are taken.

(iv) taking corrective action, i.e. action to eliminate the cause of deficiencies, in response to recurring or systematic deficiencies identified by users.

Corrective actions identified by users are discussed in the QMG. If QMG agrees with the user, necessary corrective measures are taken.

(v) taking preventive action, i.e. action to eliminate the cause of potential deficiencies, in response to potential deficiencies or problems identified by users;

Preventive actions identified by users are discussed in the QMG. If the QMG agrees with the user, necessary measures are taken.

(vi) ensuring needs and legitimate expectations of users are met.

Legitimate issues are discussed in the QMG and, if necessary, in other competent bodies of PRH.

INTERNAL REVIEW (PARAGRAPHS 21.10–21.15)

Paragraph 21.10 specifies that, in addition to a "quality assurance system for checking and ensuring compliance with the requirements set out in its QMS" [c.f. Paragraphs 21.03, 21.07], "each Authority should establish its own internal review arrangements to determine the extent to which it has established a QMS based on the above model". This model is set out by Chapter 21 as a whole [c.f. Paragraph 21.02]. Since a QMS which does not contain this provision for internal review would not meet the requirements of Chapter 21, the report under 21.17 should contain at least the information on the extent to which arrangements for internal review required by 21.10 are in place. These are as below.

Required Arrangements for Internal Review (Paragraph 21.10)

The Authority should show that arrangements are in place to ensure that:

- (a) An internal review is carried out to determine:
 - (i) the extent to which a QMS complying with the model of Chapter 21 has been established;

Internal audits are carried out.

Carrying out Management reviews is a mandatory requirement according to ISO 9001:2000.

(ii) the extent to which the Authority complies with the requirements of its QMS;

Internal audits ensure that the QMS requirements are met.

Internal audits are carried out twice a year according an approved year plan.

Management reviews are carried out at least twice a year.

- (iii) the extent to which the Authority complies with PCT/GL/ISPE.
- (b) The internal review demonstrates whether or not the requirements of the QMS and PCT/GL/ISPE are being applied consistently and effectively.

Any possible identified inconsistencies or unconformities are recorded in the audit reports. Initiatives for improvements are also reported. The QMG sees to that inconsistencies or unconformities are eliminated and monitors the progress of improvement initiatives.

Management reviews are conducted in order to ensure QMSs continuing suitability, adequacy and effectiveness. This review includes assessing audit reports and improvements and the need for changes in the quality management system, including the quality policy and quality objectives.

The internal review takes place at least once a year.

Internal audits are carried out twice a year according an approved year plan.

Management reviews are organised at least twice year.

Follow up audits by external auditors are carried out once a year.

OPTIONAL INFORMATION UNDER PARAGRAPH 21.17

Guide to Internal Review Arrangements (Paragraphs 21.11–21.15)

Paragraph 21.11 states that 21.12 - 21.15 are "proposed as a guide to the basic components of an internal review mechanism and reporting system", and are thus optional. Authorities may respond to the following points to indicate the provisions they have in place for Internal Review.

The Authority may show that the following arrangements are in place and will be used for the purpose of internal review:

(a) Arrangements providing information on conformity of S&E work; i.e. information from activities related to verification, validation and monitoring, as carried out in order to assess compliance of S&E work with PCT/GL/ISPE [c.f. point (a) under "Quality Assurance" above].

he QA system reports on observed unconformities and makes proposals for improvements and best practices.

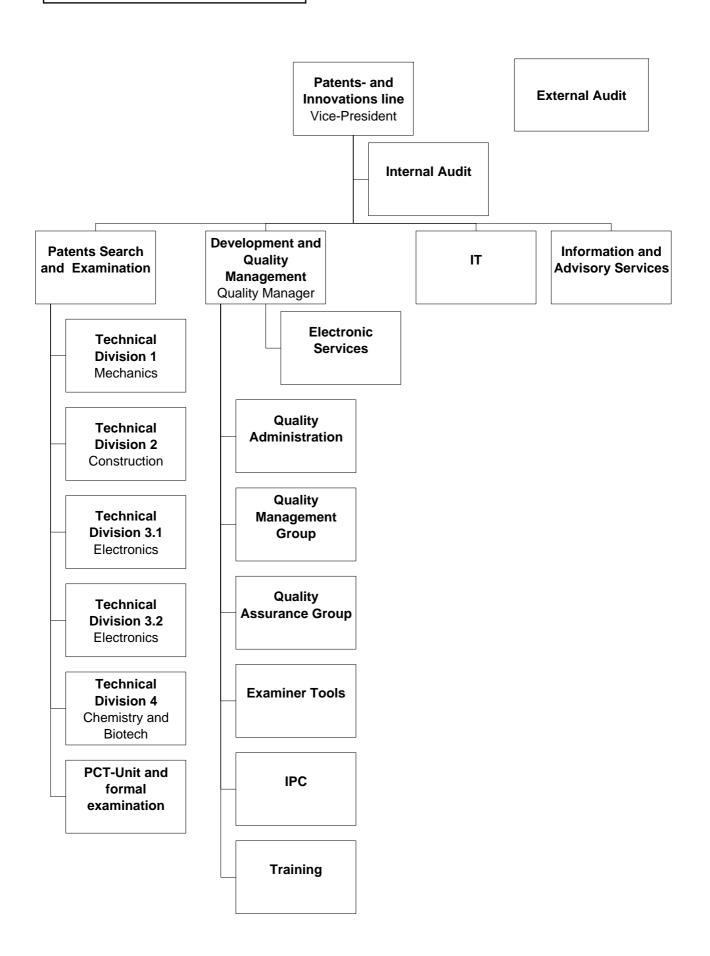
The internal and external audit systems report on observed inconsistencies and unconformities. Proposals for improvements are also reported.

(b) Arrangements providing information on the effectiveness, and the extent of implementation, of the QMS and its processes; whereby it can be established to which extent the QMS complies with the requirements of Chapter 21 and, if applicable, any other normative reference for the QMS.

The QMG monitors all reported inconsistencies, unconformities, and the progress of improvements.

External audits are organised in order to ensure maintenance and a continuous improvement of the system and conformity with both Chapter 21 and ISO 9001:2000.

[End of report]



Report FI Annex II - Manual

Operations manual

7.12.2006

Patents and innovations line

Introduction

The National Board of Patents and Registration of Finland (NBPR) is an authority under the Ministry of Trade and Industry, and its activities are governed by the Decree on the National Board of Patents and Registration of Finland (575/92, 799/92).

According to Decree 799/92, the NBPR shall have the Enterprises and Corporations Line, the Patents and Innovations Line (PAI), and the Trademarks and Designs Line. Further, the NBPR shall have the Administration unit and other units. The Board of Appeal is an independent body applying administrative legislation in connection with the NBPR.

This Operations manual describes the quality management system used by PAI in its functions. For the present, the system is only applied to the handling of PCT applications (receiving, novelty search, and preliminary examination as to patentability of international applications) among the various tasks entrusted to PAI. The quality management system has been established according to ISO 9000 standard series. The requirements for the design and development of product (7.3), purchasing (7.4), the control of monitoring and measuring devices (7.6) are not applied because these functions do not exist in the processes covered by the quality management system.

In addition to this manual, our documentation included in the quality management system comprises a quality policy and quality objectives, statutes and guidelines required in planning and activities, as well as documents and recordings required by the standards for quality management systems.

Inspecta Certification has granted 23.11.2006 certificate (No 4725-01) as proof that the quality management system of Patents and Innovations Line complies with the requirements of the standard SFS-EN ISO 9001:2000.

1. Organisation and operating principles

1.1. Mission and vision

The mission and vision of the NBPR are included in the operational and financial plan for 2007 - 2010. The mission of PAI is also put forth in the PAI strategy.

Mission of the NBPR

As an organisation specialised in industrial property rights and business and corporation activities, the National Board of Patents and Registration of Finland (NBPR) advances enterprise, innovativeness, and corporate activities both in Finland and internationally.

The NBPR fosters human capital and furthers technological and economic development by ensuring that

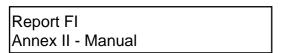
- companies, associations, and foundations are able to operate legally in Finland,
- inventors, researchers, product developers, manufacturers, and marketers are able to obtain patents, trademarks, design rights, or other forms of industrial property rights, and
- the interests of Finns are internationally protected.

Our information and advisory services are reliable and quickly accessible.

Mission of PAI

The mission of PAI includes

- handling patent applications in a flexible, fast, and cost-effective way in order that covering and high-quality
 office actions on inventions' novelty and patentability are drawn up in due time before the end of the priority
 year,
- dealing with the further processing of applications rapidly, and
- seeing to that all relevant national and international patent information is available for Finnish clients in modern form.



Vision 2008 of the NBPR

Creativity, know-how, enterprise, and collaboration are key factors for the success of our clients, as well as the basis for technological, economic, and intellectual development and wellbeing in Finland.

Our clients rely on our legal validity, impartiality, and internationally competitive quality and, through the NBPR, they are also able to fully operate in international business and the multinational innovation system.

Our service is fast, flexible, and easily accessible at our Helsinki Head Office (Innohouse), regional service points, and electronic information networks.

Our staff is the friendliest and most competent in Finland. We respect our fellow workers, we are open, and we constantly strive to improve our performance.

1.2. Values

We aim at a continuous value dialogue in the NBPR. After a discussion held and preparations made in 2004, our core ethical values were condensed into the following concepts: Service, performance, influence and wellbeing, co-operation, responsibility, and development.

Service

Our services are based on our clients' needs and their purpose is to produce added value to the operation of our interest groups both domestically and internationally.

We provide reliable, wide-ranging, and easily accessible service and consultancy.

Performance

Our operation is based on pre-set result targets, which help us to produce high-quality services effectively and profitably. The staff is committed to the operational targets.

Influence and wellbeing

We promote innovativeness, enterprise, and corporate activities.

We work together to ensure optimum interest, endurance, and wellbeing at work.

Co-operation

Our interaction with clients and other interest groups is open and active.

The operation inside the Office is based on open co-operation among the staff.

We respect gender equality, equality between all people, and each others' work.

Responsibility

Clients can rely on the objectivity and legal validity of our activities.

We operate impartially and independently. We are just and unbribable.

Development

We value know-how and support it through continuous training and development of professional skills. As experts, we develop our operations and services in both the national and international operating environment.

1.3. Strategy

Strategy of the NBPR

The NBPR strategy 2005 aims at supporting our clients' competitiveness in globalising business. The NBPR provides services and information which shall help clients to fully operate in changing operating environments in order to promote technical and economic progress in Finland.

Strategy of PAI

Within the NBPR strategy, a detailed strategy has been drawn up for PAI which puts forth a mission, operating plan, key processes, productivity targets, and features describing the structure and culture of our organisation.

Report FI Annex II - Manual

1.4. Organisation

Units

Detailed provisions on dividing the NBPR into units have been given in the rules of procedure issued by virtue of section 17 of the Decree (799/92) on the NBPR, which lays down that PAI shall have three basic units. The first unit shall handle patent issues in connection with the technical units, involving patent issues relating to legislative development and law harmonisation, checks as to formal aspects of patent applications, support functions at PAI, advisory services, and matters concerning both utility models and EPC and PCT. The second unit shall act as a development unit, which is responsible for the technical development of the Line's working processes and for the maintenance and improvement of the IT systems. The third unit shall be a library and information service unit assigned with the task of maintaining search and examination material and a library of other documents, attending to clients in issues relating to patent information, and assisting other units outside PAI in various tasks whenever necessary.

The division of PAI into divisions, sections, and other subunits including the tasks of these units are shown in an organisation chart. The search and examination of PCT applications and national patent applications are conducted by the technical divisions, which are: 1. Machine division, 2. Construction division, 3. Electricity division (3.1. Physics, electrical engineering, and information technology, 3.2 Telecommunications technology), 4. Chemistry division. The PCT unit is responsible for the examination as to formal requirements of PCT applications. The minutes of technical division meetings have been stored on the IMS internal level "Division meetings".

Staff

Job descriptions define the tasks entrusted to the employees of the NBPR. They also specify the qualifications required, i.e., which education, work experience, and skills are required in each position.

Examiners and senior examiners carry out novelty searches and patentability examinations of patent applications. Vice President grants a new examiner an independent power of decision in patent issues according to item 24 of the rules of procedure of the NBPR when both Vice President and the head of division regard the examiner as competent. Vice President may promote an examiner to a senior examiner on the proposal of the head of division when the examiner in question has acquired a very in-depth knowledge of patent issues. Besides search and examination work, examiners' and senior examiners' jobs include other tasks, too. These tasks and the qualifications required here are specified in individual job descriptions.

Internal levels

Division meetings

Toimistokokoukset

1.5. Tasks

The main function of the Patents and Innovations Line is to examine the novelty and patentability of inventions described in patent applications and to register utility models and semiconductor topographies. As the NBPR is a Receiving Office, PAI checks that international patent applications filed with us meet the prescribed formal requirements. In its capacity as an international authority, PAI also carries out international novelty searches and preliminary examinations as to patentability.

The tasks of the basic units of PAI are specified in the rules of procedure issued by virtue of section 17 of the Decree (575/92) on the National Board of Patents and Registration of Finland.

2. Quality policy

Creativity, know-how, enterprise, and collaboration are key factors for the success of our clients as well as the basis for technological, economic, and intellectual development and wellbeing in Finland. Our clients rely on our legal validity and internationally competitive quality and, through the NBPR, they are also able to fully operate in international business and the multinational innovation system.

Our clients can rely on that

- our service is easily accessible, and
- it is polite, impartial, and equitable;
- our operation is fair, reliable, open, and transparent;



- our searches and examinations are extensive and have high quality; and
- decisions are made on time, and they are precise and clear.

Our staff

- is skilful, friendly, and open,
- respects gender equality, equality between all people, and each others' work.
- constantly strives to improve its performance,
- takes part in improving the working environment and working methods, and
- is aware of the significance of the quality policy and follows it.

Our management

- pays attention to the points of view of the staff in its decision-making,
- informs effectively and openly of its actions,
- puts decisions into practice and encourages the staff to take independent responsibility for their work,
- agrees with the staff on individual targets and supports reaching them,
- helps the staff to use their resources by providing training, professional development opportunities, and a good working environment,
- motivates the staff to do their best and sees to that the staff is rewarded for good results,
- · sees to that the practices are improved in case of errors or deficiencies,
- · takes care that the resources are adequate, and
- considers the quality policy in annual reviews.

We continuously improve our performance

- by paying attention to both clients' needs and wishes and to the changes in the operating environment,
- by taking part in international co-operation,
- by encouraging everybody to make proposals for improvement,
- by improving our working methods and practices, and
- by developing our IT systems.

3. Responsibility and commitment of the management

Responsibilities and authorities

Vice President is in charge of the operations of PAI. According to the job description, Vice President is responsible for the strategy, economic balance, and activities of PAI in order to reach the strategic targets, with special emphasis on factors which have effect on quality.

The PAI management group supervises the Line's activities. The composition of the management group and its tasks are given in the job description for the management group. The heads of divisions, sections, and subunits are responsible for the duties defined in respective job descriptions.

Commitment

PAI Management

- defines the quality policy to be followed in the Line and implements it,
- acts as part of the Line's quality management system, and
- · communicates the quality policy internally and externally.

Management reviews

The Management Group carries out reviews twice a year, when

- the quality feedback from the previous review period is analysed,
- · changes and improvements in PAI's activities and quality management system are decided on, and
- PAI's quality policy and quality targets are revised.



The matters to be taken up in reviews are given on the agenda.

Documents

- Documents for the quality management system
- Management review agenda
 - Johdon katselmusten esityslista

4. Processes

4.1. Process chart

The process chart for the Patents and Innovations Line showing the Line's processes and working environment is available in section Processes of the IMS program. Clients' needs, requirements, and expectations are given as the basis for PAI's activities in the chart. In its functions, PAI follows patent law and international agreeements (EPO, WIPO).

Processes which serve clients and produce added value for them constitute the core processes. The core processes of PAI are: handling of national patent applications, handling of PCT applications, registration of utility models, and running of the Patent Library and Advisory Services. Support processes are internal processes within the organisation which support the core processes and enable their function. PAI's support processes are: leadership and influence, quality management, training, IT services, and administration.

The key processes include the core processes and the most important support processes. The key processes of PAI are: handling of national patent applications, handling of PCT applications, registration of utility models, running of the Patent Library and Advisory Services, as well as leadership and influence.

So far, the PAI quality management system includes only one core process, the handling of PCT applications. This manual and section Processes of the IMS program describe the handling of PCT applications, leadership and influence, quality management, training, and IT services.

Processes

Patents and Innovations Line

Patentti- ja innovaatiolinja

4.2. Handling of national patent applications

PAI handles and examines applications for patents to be granted in Finland. Patents may only be granted for industrially applicable inventions which are new in relation to what was known before the date of filing of the patent application and which also differ essentially therefrom.

The steps of the handling of national patent applications are:

- receipt of applications,
- examination as to formal requirements,
- measures before a novelty search.
- novelty search,
- assessment as to patentability,
- drawing up an office action,
- further measures after the first office action,
- approval or rejection of the application, and,
- possibly, an opposition procedure.

4.3. Handling of PCT applications

The Patents and Innovations Line functions as a Receiving Office (RO), which receives international patent applications, as an International Searching Authority (ISA), and as an International Preliminary Examining Authority (IPEA) under the Patent Co-operation Treaty (PCT). The NBPR functions as a searching and examining authority as of 1 April 2005. PAI searches and examines such applications in which the NBPR has been selected as the Searching and / or Preliminary



Examining Authority.

A detailed description of the process is available in section Processes of the IMS program.

Receiving Office (RO)

Applicants who want their inventions to be made the subject of an international novelty search or a preliminary examination as to patentability file their applications to the PatRek Client Service or the PCT Unit. The PCT unit then forwards the application to the WIPO and a search copy of the application both to the searching authority specified by the applicant and to the WIPO.

The Receiving Office handles the applications in the following steps:

- receipt of applications,
- examination of applications as to formal requirements,
- examination as to importance to the national defence, and
- checking and sending forward of applications.

International Searching Authority (ISA)

PAI conducts a novelty search of an invention described in an international application after receiving the search copy of the application from either the RO or the WIPO. The aim of the search is to issue an opinion on the novelty, inventiveness, and industrial applicability of the invention according to the patent claims and to inform the applicant of the defects in the application in order that the applicant can take necessary further measures. A search report and a written opinion are drawn up on the basis of the search results.

The ISA handles the applications in the following steps:

- receipt of a search copy and preparatory measures,
- measures before a novelty search,
- novelty search,
- drawing up a search report and a written opinion, and
- checking and forwarding of the filled-in forms.

International Preliminary Examining Authority (IPEA)

PAI conducts a preliminary examination as to patentability of an invention described in an international application after receiving the applicant's request for preliminary examination. The purpose of the examination is to issue an opinion on the patentability of the invention according to the patent claims, i.e., on the invention's novelty, inventiveness, and industrial applicability. On the basis of the examination, PAI draws up an International Preliminary Examination Report (IPER). If necessary, PAI issues one or more written opinions before drawing up the Examination Report.

The IPEA handles the applications in the following steps:

- · examination as to formal requirements,
- preliminary examination as to patentability,
- drawing up of written opinions,
- · drawing up of an International Preliminary Examination Report, and
- checking and forwarding of filled-in forms.

Processes

Handling of PCT applications International Preliminary Examining Authority International Searching Authority Receiving Office

- PCT-hakemusten käsittely
- Patentoitavuuden esitutkimus- viranomainen
- Uutuustutkimus- viranomainen
- Vastaanottava viranomainen



4.4. Support processes

Leadership and influence

The target of the PAI management is to lead the Line according to the PAI strategy in such a way that it carries out the official activities under the Patents Act and Patents Decree in a high-quality manner, rapidly, and cost-effectively, and that the Line, through its functions, furthers technological development in Finland.

The PAI management also supervises the interests of Finnish industry and business when international patent systems are developed.

The PAI management's responsibility and commitment are described in chapter 3 of this manual.

Quality management

The purpose of quality management is to develop the activities of PAI in order to improve quality and productivity, as well as client satisfaction. The process is described in detail in section Processes of the IMS program and in chapter 6 of this manual.

Training

The purpose of training is to maintain and improve the staff's professional skills, to guide new employees, and to introduce employees to new tasks when job descriptions are changed. New examiners are given training according to a qualification programme for examiners, and they become familiar with the work under the guidance of a personal mentor. Independent power of decision in patent matters is granted to examiners according to item 1.4 of this manual. The staff maintains and develops their professional skills by taking part in courses arranged by PAI and the NBPR as well as external quarters.

A working group on training issues is responsible for planning and implementing the staff training.

IT services

The purpose of the IT services is to meet the requirements and expectations specified in the service agreement concerning the data systems used by PAI. The task of the IT services is to ensure a disturbance-free handling of applications, fluent searches and examinations, and reliable patent administration. The PAI staff, our strategic cooperation partners, and our active involvement in the European development of IT services within the EPO ensure that we have at our disposal the resources required for providing the IT services. The Data Administration Unit of the NBPR Administration is in charge of the IT services.

Administration

The Administration of the NBPR is responsible for PAI's administrative matters according to the NBPR rules of procedure. The Administration assists the President, Senior Vice President, and Vice Presidents, being responsible for planning, finances, human resources, international and legal affairs, communications, and data administration, to the extent those issues have not been delegated to the Lines or other units. Besides, the Administration assists the President in developing the Office and in implementing the set targets.

Processes

IT services Leadership and influence Training Quality management

- F IT-palvelut
- Johtaminen ja vaikuttaminen
- Koulutus
- Laadunhallinta

5. Targets

5.1. Performance and productivity targets



Targets for the productivity of the NBPR's activities are set every year in result agreements between the Ministry of Trade and Industry and the NBPR. In view of effectiveness, the result agreement sets targets for the average handling times in the various services, the productivity of work, and costs per unit.

The targets established in the result agreement are converted into ones concerning each Line, which are confirmed by the President. PAI's performance and productivity targets are presented in the performance and productivity system, which gives estimated figures for the next few years as to

- the number of applications not handled at the beginning and at the end of the year
- o the number of new applications per each year
- o the number of outputs
- person-workyears
- productivity
- the increase in productivity
- o average processing times

5.2. Targets for the handling of PCT applications

Speed

The Patent Co-operation Treaty sets a time limit for completing an international novelty search. The time limit for establishing the international search report is the one expiring later of the following (PCT Rule 42.1):

- three months from the receipt of the search copy by the International Searching Authority, or
- nine months from the priority date (from the international filing date, if priority not claimed).

The target is that

- the examiner completes the novelty search and draws up the search report one month before the above time limits in 90% of all applications,
- The PCT Unit sends forward all the novelty searches by the above time limits, and
- the average processing time for an application where priority is not claimed is six months.

The time limits do not concern applications where the invention lacks unity or the sequence list is missing.

Quality

The working group on quality assessment controls the quality of the processing of PCT applications by spot checks. The working group determines a quality class of each process on the basis of the quality assessment criteria. As regards novelty searches, the target is that

- not more than 5% are unsatisfactory,
- not more than 15% (including the above) must be improved, and
- at least 85% are faultless.

Documents

- Documents for the quality management system
- ISA quality assessment criteria
 - o <u>ISA-laadunvarmistuskriteerit</u>

5.3. Targets for the handling of national applications

Speed

The processing time targets for applications where priority is not claimed for patents to be granted in Finland are:

- the processing of at least 80% of the applications is completed within three years,
- in case of at least 80% of the applications, the first office action is issued within seven months from the filing date,

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- after the applicant's reply, at least 90% of second office actions is issued within one year, and
- other further measures (the notice according to section 19 of the Patents Act, forwarding for printing) are carried out without delay.

The processing time targets for foreign applications entered into the national phase in Finland are:

- as of 2008, the processing of at least 80% of the applications will be completed within six years,
- after the applicant's reply, at least 90% of second office actions is issued within one year, and
- other further measures (the notice according to section 19 of the Patents Act, forwarding for printing) are carried out without delay.

Quality

The working group on quality assessment controls the quality of novelty searches and examinations as to patentability by spot checks. As regards novelty searches, the target is that

- not more than 5% are unsatisfactory,
- not more than 15% (including the above) must be improved, and
- at least 85% are faultless.

5.4. Target follow-up

The PAI management decides on quality targets in annual management reviews on the basis of reports from the quality management group. The PAI management monitors the outcome and decides on considerable changes to be made to the organisation and processes.

The quality management group monitors the outcome of the quality targets. If necessary, it makes proposals, changes, and improvements in the processes, guidelines, training, and systems. The quality management group may make proposals to the PAI management in order to revise the quality targets.

The targets of PAI and their outcome and development trends are presented on the BSCnet result card (Innonet - eServices - Management data system - BSCnet - Result cards - Patent).

6. Quality management system

6.1. General aspects

The PAI quality management system is described in the organisation chart for the quality management system. The purpose of the system is to develop the functions of PAI in order to improve quality and productivity and to increase client satisfaction.

The quality manager is in charge of the implementation and continuous development of the quality management system. The quality management group assesses and develops the function of the quality management system and follows up the outcome of the quality targets. The working group on quality assessment controls the quality level of examiners' work. Heads of division and approving examiners carry out continuous quality assessment by monitoring and checking examiners' decisions and opinions.

Once a year, the management group carries out a review where decisions are made on changes and improvements in PAI's functions and the PAI quality policy and quality targets are revised (Chapter 3: Responsibility and commitment of the management).

6.2. Quality management group

The quality management group assesses and develops the function of the quality management system and follows up the outcome of the quality targets. If necessary, it makes proposals, changes, and improvements in the processes, guidelines, training, and systems. It may also submit proposals to the Line management in order to revise the quality targets. Further, the quality management group makes preparations for both management reviews and internal and external audits.

The sources of information for the quality management group as a basis for decision-making are:

Report FI Annex II - Manual

- performance and productivity statistics,
- o processing times,
- reports from internal and external audits,
- o reports from the working group on quality assessment,
- o quality assessment reports from heads of division,
- o client feedback, and client satisfaction surveys.

The quality management group meets at least four times a year, in general, after internal and external audits. The matters to be taken up at the meetings are given on the agenda.

The quality management group consists of the quality chief (chairperson), heads of the units, and persons in charge of quality.

The minutes of the quality management group meetings are available on the IMS internal level "Quality management group".

Documents

- Documents for the quality management system
- •
- Agenda for the meeting of the quality management group
 - o Laatujohtoryhmän kokouksen esityslista

Internal levels

Quality management group

laatujohtoryhmä

6.3. Working group on quality assessment

The purpose of the Working group on quality assessment is to keep up the good quality of the searches, examinations, decisions, reports, and opinions by examiners. The group consists of nine examiners with extensive work experience. They come from all the technical divisions of PAI and, thus, represent different branches of technology.

The working group uses random sampling and annually checks at least two applications by each examiner. One of the applications should be a PCT application. On the basis of the decisions, reports, and opinions given by the examiner in the different steps of the handling process, the working group analyses whether the examiner has followed the given quality criteria, quality standards, and guidelines. The estimated time for analysing one application is from four hours to one workday. The working group measures the quality level of searches and examinations by means of the criteria given in the quality targets. The working group determines a quality class of each application process on the basis of the quality assessment criteria.

The working group on quality assessment summarises the analysis results and quality measurements. The working group suggests remedies and preventive measures. The working group reports on the results of its work to the quality management group.

The matters to be taken up at the meetings of the working group on quality assessment are given on the agenda.

The minutes of the working group meetings are available on the IMS internal level "Working group on quality assessment".

Documents

- Documents for the quality management system
- •
- Agenda for the meeting of the working group on quality assessment
 - o Laadunvarmistustyöryhmän kokouksen esityslista

Internal levels

Working group on quality assessment

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laadunvarmistustyöryhmä

6.4. Continuous quality assessment

Quality assessment by heads of division

Heads of division daily monitor the decisions and opinions given by examiners. The heads of division

- o control that the guidelines are followed,
- o control that the work done reaches the agreed-on quality level.
- o control that PCT forms and check lists have been filled in duly,
- o give feedback to examiners,
- o gather information on faults and deficiencies in the application process, and
- report on the quality level of the decisions and make proposals for remedies and preventive measures to the quality management group.

The heads of division fill in a check list for heads of division for every PCT application they check.

Quality assessment by approving examiner

Two examiners work in co-operation on the search of a PCT application: one who carries out an international novelty search and another, approving examiner, who checks the work done by the first examiner. The approving examiner looks into

- o the application,
- o the search plan,
- o the search strategy,
- o the search results,
- o the search report, and
- the written opinion.

The approving examiner controls that

- the search plan is appropriate,
- o the search is extensive and of high quality,
- o the examiner's view on novelty, inventiveness, and industrial applicability is correct,
- the written opinion has been drawn up according to Chapter 6 of the instruction "International novelty search", and
- o the forms have been filled in correctly.

The approving examiner informs the examiner who conducted the search of the faults and deficiencies he/she has noticed, whereafter the person who conducted the search makes the necessary revisions before forwarding the results to the head of division. The approving examiners fill in an ISA check list for approving examiners for every ISA process they have checked and an IPEA check list for approving examiners for every IPEA process they have checked.

6.5. System maintenance

Quality chief

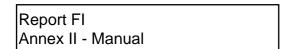
The quality chief is in charge of the implementation and continuous development of the quality management system.

The quality chief represents the PAI management and reports to the management on the system's functionality and necessary improvements to be made to it.

The quality chief chairs the quality management group and takes part in working groups entrusted with the development of the activities and quality improvement. The quality chief takes part in the meetings of the Contact committee (Item 7.4).

Persons in charge of quality

Two persons are in charge of quality, and their task is to coordinate the maintenance and development of the quality management system.



The persons in charge of quality are members of the quality management group.

7. Monitoring and development of the activities

7.1. Development of the activities

Continuous development

PAI uses a quality management process in order to continuously improve its processes and quality management system. The organisation of the quality management system and the quality management process are, respectively, presented in Chapter 6 of this manual and in section Processes of the IMS program.

In continuous development, we also take remedying and preventive measures.

Remedying measures

The purpose of the remedying measures is to eliminate the reason(s) for detected errors or deficiencies or other unwanted situations. Remedying measures are taken to prevent repeated errors.

We get information on errors and deficiencies from client feedback and client surveys, internal and external audits, the working group on quality assessment, heads of division, approving examiners, as well as from job satisfaction surveys, internal feedback and complaints. The quality chief and quality management group look into the reasons for errors and deficiencies and assess which of them need to be corrected. The owner of the process is responsible for determining the necessary measures and for seeing to that they will be carried out. The quality chief and quality management group ensure that sufficient measures are taken.

As regards nonconformities detected in internal and external audits, we proceed according to the guidelines (Items 7.2. and 7.3.).

Preventive measures

The purpose of the preventive measures is to eliminate the reason(s) for detected errors or deficiencies or other unwanted situations. Preventive measures are taken to prevent, in advance, events from occurring.

Processes

Quality management

Laadunhallinta

7.2. Internal audits

PAI carries out internal audits at regular intervals in order to find out whether the quality management system comes up to the plans, standards, and the requirements set by the organisation itself, and whether it is implemented and maintained in an effective way.

Guidelines have been issued for the internal audit procedure. The guidelines describe how internal audits shall be planned, carried out, and reported on, and how remedying measures are controlled.

Documents

- Documents for the quality management system
- Guidelines for the internal audit procedure
 - o Sisäisen auditoinnin menettelyohje

7.3. External audits

The quality chief and quality management group choose an independent and impartial certification body to conduct external audits. On the basis of ISO 9001, the auditor assesses PAI's ability to meet the requirements established by clients, law, and our organisation itself.

External audits take place at intervals of six months. Each time, a part of the quality management system is audited so that the whole system will be audited within three years.

The quality chief and quality management group plan the audits together with the auditor. The auditor conducts an audit and draws up an audit report on the results and a nonconformity report on the nonconformities. Then, the reports are forwarded to the quality chief and the owners of the process. The owner shall find out the reasons for the nonconformities and see to that the errors are corrected immediately, whereafter the correction measures are entered into the nonconformity report. The auditor checks and approves the correction measures.

The audit results are gone through in the quality management group and in management reviews.

7.4. Client feedback

The quality management group gathers, analyses, and uses the feedback concerning client satisfaction. The information sources include: direct communication with clients, written feedback from clients on the handling of the searches and examinations of applications, feedback from the Contact committee, client satisfactions surveys, and the appeals to the Board of Appeal and to the Supreme Administrative Court.

Direct communication includes client contacts by phone or e-mail due to issued decisions and opinions, as well as informal discussions at training events, fairs, etc.

Clients may provide feedback by mail or by e-mail. You can also give feedback in electronic form through our website. Feedback mail is first entered into the diary at the PatRek Client Service. Then, it is forwarded to the management of the NBPR and, if necessary, to the unit concerned. A client complaint concerning the activities of PAI is forwarded to that unit and official who had previously dealt with the matter. Both complaints and responses given are forwarded to the quality chief for information. If necessary, the quality chief takes up the matter with the quality management group. The handling of client complaints within PAI is described in detail in the instruction "Client complaints". Feedback documents are filed according to the "Archive formation plan" (Item 8.1).

We receive client feedback on the quality of searches and examinations through the Contact committee, which is an interactive forum between PAI, patent agents, and patent engineers within industry. The composition and duties of the Contact committee are given in the job description.

Both the client satisfaction target level and carrying out a client satisfaction survey are agreed on in a result agreement between the Ministry of Trade and Industry and the NBPR. The Administration (Planning and development) of the NBPR is responsible for surveys. The results of the surveys are looked into per units. The targets for PAI clients' satisfaction and their outcome as well as development trends are presented on the BSCnet result card (Innonet - eServices - Management data system - BSCnet - Result cards - Patent).

Heads of division monitor the decisions of the Board of Appeal and the Supreme Administrative Court and report on them to the quality management group.

7.5. Job satisfaction and equality

The staff's job satisfaction is annually measured by means of a job satisfaction barometer. The results are then presented in the NBPR's human resource accounts, which are available on Innonet on page "Planning and monitoring of the activities". The Administration (Planning and development) of the NBPR is responsible for the surveys. The results are evaluated per units. The targets, their outcome, and the development trends concerning the job satisfaction within PAI including the satisfaction with its management and with the flow of information are presented on the BSCnet result card (Innonet - eServices - Management data system - BSCnet - Result cards - Patent).

The NBPR has drawn up an equality plan according to the Equality Act. The plan came into force on 1 March 2006. It is available on Innonet on page "Planning and monitoring of the activities". The Equality committee annually assesses the implementation and results of the measures taken according to a previous plan. At the same time, the plan is updated, if necessary, and new targets for a year onwards are set. The Equality committee annually reports on the results and new targets to the Co-operation Committee and Management Group of the NBPR.

8. Documentation

8.1. Documents and their management

The Archives Law (831/1994) provides that national offices shall have an archive formation plan. The plan of the NBPR lists all documents received by the NBPR due to its tasks and drawn up in connection with its activities, as well as the



information most relevant to document management. Thus, the PAI documents also appear from the NBPR's archive formation plan irrespective of the recording form, as well as the documents'

- subject matter (why it exists and what is the name of the creator)
- registration (in the diary, another register)
- · filing manner,
- · place of storage,
- time of storage,
- publicity; basis and time for concealment of non-public documents,
- the directories through which documents are found, and
- interrelationships between data and data contents.

The archive formation plan is maintained and used according to the guidelines of the National Archives Service. The document management within the Administration of the NBPR is responsible for the archive formation plan.

Non-public documents are stored in a separate locked room. For gathering any copies of them to be destroyed, there are locked bins on each floor.

8.2. Documentation for the quality management system

The documentation for the quality management system comprises: a quality manual, quality policy, and quality targets; the statutes and guidelines necessary in planning and actions; and documents and recordings required by the standards for quality management systems.

The documents and recordings related to the quality management system are maintained and stored by means of the IMS program. Other statutes and guidelines necessary in planning and actions are available via the data systems of the NBPR (PAT-Intra, Innonet, Internet). The most important statutes and guidelines and their addresses are listed at the end of this manual (Chapter 9). The operating guidelines related to the processes including their addresses are available in the IMS Section Processes.

The updated version of the Working manual approved by the quality chief including the date of approval can be viewed in IMS. The quality policy and quality targets agreed on by the PAI management are presented in the Working manual (Chapters 2 and 5).

The documents for the quality management system, such as procedural guidelines and agendas, have been recorded in section Documents of the IMS program. Here, you can find the names of the persons who drew up, controlled, and approved each document, the number of the version, and the times for the measures.

The recordings of the quality management system have been stored in section Recordings of the IMS program. Here, you can find the names of the persons who drew up and approved each document, and the times for the measures. The recordings include the minutes of meetings, annual plans for internal audits, audit reports, and the reports of the Working group on quality assessment. The recordings cannot be amended after their approval.

9. Statutes and guidelines

9.1. Domestic statutes

In Finland, the patenting of inventions is regulated by the Patents Act (550/67 incl. amendments), the Patents Decree (669/80 incl. amendments), and the Patents Instructions.

The registration of utility models is regulated by the Utility Model Act (800/91 incl. amendments), the Utility Model Decree (1419/91 incl. amendments), and the Utility Model Instructions.

9.2. Procedural guidelines

Patent manual

The most important guidelines concerning the handling of applications have been presented in the Patent manual, the purpose of which is to harmonise and speed up the search and examination of patent applications and to ensure that every step of the process is carried out in a high-quality manner.



The Patent manual includes the guidelines for the handling of national applications, the handling of utility model applications, and for conducting international novelty searches.

For every step in the handling process, the Patent manual states the contents requirements and procedural guidelines, according to which the applications are handled by the NBPR. The purpose of the guidelines is to advise the staff in charge of the handling of the applications in such a way that they are aware of the handling procedure and can independently apply the guidelines in different situations.

Guidelines for the handling of patent applications

The manual "Guidelines for the handling of patent applications" includes detailed instructions for how examiners shall in practise carry out the measures to be taken as to national patent applications.

Other instructions

Other instructions have been gathered to the Intranet page "Instructions to examiners".

9.3. International agreements and guidelines

Finland has acceded to the following international agreements: European Patent Convention EPC (amendments) and Patent Co-operation Treaty PCT (articles, rules, amendments).

The following Wipo guidelines and standards are followed in the handling of the PCT applications in addition to the above agreements: PCT International Search and Preliminary Examination Guidelines.

PCT Receiving Office Guidelines and

WIPO Standards.