#### 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: Swedish Patent and Registration Office

on: **2006-12-18** 

# Documents referred to in this report:

[list any documents which appended to the report for information or publicly available documents which are referred to]

# 1) Organization

Process oriented organization
Process chart
Explanations
Hierarchical organization (responsibility)
Organigram
Explanations

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

PRV is currently implementing a quality management system adapted for ISO 9001 certification by the end of 2007. The QMS of PRV is intended to cover all parts of our business where the role of RO, ISA and IPEA are central parts.

An important part of the system is to describe our organization in a process oriented view in order to focus the quality system on our processes and products as complement to our hierarchical organization based on area of responsibility. Se appendix.

## 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, Formalities procedures, feedback and communication channels required to underpin search and examination (S&E);
- (b) incorporates a quality assurance scheme for monitoring compliance with these basic requirements and with 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;
  - (ii) means for ensuring that recruited S&E staff have the necessary technical qualifications;
- (iii) means for ensuring that S&E staff have language skills, or have access to supporting translation arrangements, as necessary to meet Rule 34.
- (b) Adequate quantity and skills of Formalities staff to support S&E.
- (c) Provision of appropriate equipment and facilities to support S&E.
- (d) Provision of the minimum documentation supporting S&E, as referred to in Rule 34.
- (e) Provision of up-to-date work manuals. These must include explanations of:
  - (i) quality criteria and standards;
  - (ii) descriptions of work procedures;
  - (iii) instructions ensuring that the work procedures are adhered to.
- (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.
- (g) Continuously monitoring and identifying resources, other than staff, required to deal with demand and comply with quality standards for S&E.
- a) The SPRO has a total of 150 examiners, divided into 3 divisions: Mechanics, Electricity and Chemistry. Each division is divided into 3-4 directorates and each directorate is divided into technical groups.
- i)
  Demand, production and productivity are closely monitored on a weekly basis for every technical group, and every month for directorates and divisions. Dynamic allocation of resources is possible only if in accordance with technical and language qualification requirements.

A computer based monitoring system concerning demand, combined with productivity algorithms, identifies resources needed at different technical groups or directorates at any

Report based on template T21-17 as adopted May 2006

given time. Additional information from a competence profile system and regular audits give management control over the dynamic allocation of resources ensuring that allocation complies with the quality standards for search and examination.

- Employment requirements guarantee the technical and language qualifications of one individual to search and examine within the technical field of at least one technical group. Search and examination staff passes through an internal educational program including several steps of examination. An Individual competence plan is renewed every year in order to se that technical competence is remained at a satisfactory level.
- iii) Search and examination staff have language skills according to the PCT regulations. Individual training programs help keeping language skills updated. Staff are also supported by computer based translation tools and if necessary the option of using external translation experts.
- b) Formalities personnel and patent assistants

The technically skilled staff is supported by the Formalities directorate as well as the Legal specialist section. The Formalities directorate has a PCT specialist group appropriately trained/skilled for supporting technical staff in any Formalities issue. The legal specialist section supports both the Formalities directorate and the technical directorates in PCT legal issues and also ensures that any changes in Formalities or legal aspects are incorporated into the organization as changes in guidelines and work-manuals.

c) The SPRO has appropriate equipment and facilities, IT hardware and software, to support the search and examination process. The functionality and availability of IT support is monitored and presented online to facilitate the search and examination process. In addition to in situ development the SPRO has a close collaboration with the EPO for the development of search tools and IT support in order to achieve harmonization.

#### d) Minimum documentation

The SPRO possesses or has access to a vast amount of documentation that exceeds the minimum documentation requirements set by the PCT and the Regulations. Most of the documentation can be accessed online. The documentation and library section monitor changes and supply updated online magazines and databases in all technical areas. The library section uses annual feedback forms to ensure that all examiners have fast access to all needed documentation, PL as well as NPL.

#### e) Up-to-date work manuals provided online through intranet

All examiners have online access to interlinked in-house PCT, PCT –guidelines, PCT-Regulations and work manuals for the different steps of the request handling process. Guidelines and manuals are kept up-to-date by specialized groups for both the search and the examination procedures.

## f) Training and development program

Examiners and Formalities staff takes part in an effective initial training and development program. They are approved through different level examination tests to ensure they acquire and maintain the necessary competence requirements. During this period the examiner is under the guidance of a tutor, who is responsible for the results of the examiner. Detailed written training material and online training programs support the in-house training. Renewal and updating courses and seminars are held on a regular basis and initiated by either the quality manager, as a result of quality checks, or by management in response to new situations or guidelines. Directors provide individual education programs, in consultation with the individual, concerning both IPL and technical aspects. The educational programs include; work shops (in-house), examiner exchange, in-house/ external seminars and courses. An extensive cross search/examining program has been developed to ensure continuity and quality.

g) The infrastructure for monitoring and identifying resources, other than staff, required to deal with demand and comply with quality standards is the supporting structure of our patent process i.e. GURU, PUB, Patent experts and process group (See appendix)

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

Provide information on those Formalities 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.
- (b) Coping with fluctuations in demand and backlog management.

#### (a) and (b)

All search and examination requests are monitored, using an alert system with internal time limits in order to give an alert in cases of requests concerning risk of delay. Corrective action is taken. There is a follow up system with feedback reports on any late requests.

Demand and backlog data is monitored at individual/technical group level.

# 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.
- (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.
- (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;
- (ii) those actions taken to eliminate the causes of deficient S&E work and prevent the deficiencies from recurring.
- (d) Activities ensuring the continuous improvement of established processes underpinning the issue of S&E reports.
  - a) PCT quality checks
    - i. Second pair of eyes quality review in accordance to computer based quality control software. The check is done in all applications by another examiner in the same technical group.
    - ii. Patent expert checks. Patent experts checking all decisions and also reviewing S&E quality on a regular basis.
    - iii. Spot checks by quality control function.
  - b) The performance of the QMS itself is analysed separately by internal-, external audits and monitored by quality controller. (Our Quality assurance procedures deal with the patent process and our end products.)
  - c)
- i. Deficiencies of products i.e. S&E work is corrected prior to expedition, when detected by the quality checks.
- ii. All deficiencies are reported. A specialized process group (see appendix) considers the possible causes and the parts of the process in need for development in order to eliminate and prevent the deficiencies or that they recur.
- c) The process group and the process council, lead by the process owner has as main task to continuously improve the process in order to achieve products in compliance with regulations, standards and customer needs. Input to this process is the quality assurance procedures discussed above, the customer feedback and other measurements done by the control function.

# 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;
- (ii) corrective action, i.e. action necessary to prevent recurrence, is identified and implemented;
  - (ii) best practice is identified, disseminated and adopted.
- (b) 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.
- a) The result from the quality checks is analysed and communicated internally as well as at customer meetings.
  - i) Deficiencies of S&E work is corrected immediately after identification together with feedback to examiner. In case of interpretation difficulties patent expert or the legal section is involved to explain the underlying causes.
  - ii) Corrective actions implemented by the process group are always informed about on the intranet and specialised information is given to concerned parties.
  - iii) Patent experts from all technical areas discuss best practice and disseminate their knowledge to the different directorates.
- b)
  The SPRO, especially the Formalities directorate and the legal section, has very good communication with the WIPO regarding feedback on the work that is done within the office.

# 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.
- (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.
- (c) Monitor and react to user needs and feedback, including:
  - (i) measuring user satisfaction and perception;
  - (ii) handling complaints;
  - (iii) correcting deficiencies identified by users;
- (iv) taking corrective action, i.e. action to eliminate the cause of deficiencies, in response to recurring or systematic deficiencies identified by users.
- (v) taking preventive action, i.e. action to eliminate the cause of potential deficiencies, in response to potential deficiencies or problems identified by users;
  - (vi) ensuring needs and legitimate expectations of users are met.

# (a) Applicant and examiner

In invitations and notifications the name of the examiner is given as well as the telephone number, fax number and visitor address to the Office. In Written Opinions and reports the name of the examiner and the telephone number to the office are given. The e-mail address to the Office can be found on our web site. Examiners are encouraged to take contact with the applicant by mail or phone in order to promptly make clear all ambiguousness.

# (b) Guidance and information to the users

The customer service centre gives answers to questions of general character and if no answer can be given, the question is passed over to an expert. The communication channels that can be used are a personal visit to the office, telephone, fax and e-mail. Specific information about the customer service centre is available on the homepage.

As regards PCT, our commission service arranges courses at different levels (orientation course, advanced course and course for assistants).

At the web site, we give general information on how to apply for patent protection in other countries and for PCT-matters there is a link to the WIPO web site and more specifically to the homepage for PCT.

#### (c) Monitor and react to user needs and feedback

- i) Measurement of user satisfaction and perception is done by recurrent customer surveys every second year.
- ii) All complaints dealing with the handling of applications and the performance of the work done within the office is handled by our Process owner (see organization in appendix). All complaints are taken care of carefully and an investigation is normally carried out in all cases. The customer will get a report on the complaint based on the investigation that

has been undertaken. In some cases, if the investigation shows that the SPRO has made an obvious mistake, we can refund fees that the applicant has already paid for their application. iii-vi) corrections, preventions of all deficiencies in response to users are handled and communicated by the process owner.

## 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;
  - (ii) the extent to which the Authority complies with the requirements of its QMS;
  - (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.
- (c) The internal review takes place at least once a year.

#### **Internal Review**

The PRV has not yet implemented all parts of our QMS and no internal review has been carried out. However internal auditors are being trained and audits are scheduled for February 2007. Internal reviews will take place at least twice a year starting 2007 and every third year external audits will take place in order to achieve and maintain ISO 9001 certification.

#### Control function

The control function is responsible for controlling the extent to which the QMS complies with ISO 9001 requirements as well as to the model of chapter 21.

#### 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].
- (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.

[End of report]

# Organisation of the Patent department at the Swedish Patent and registration office

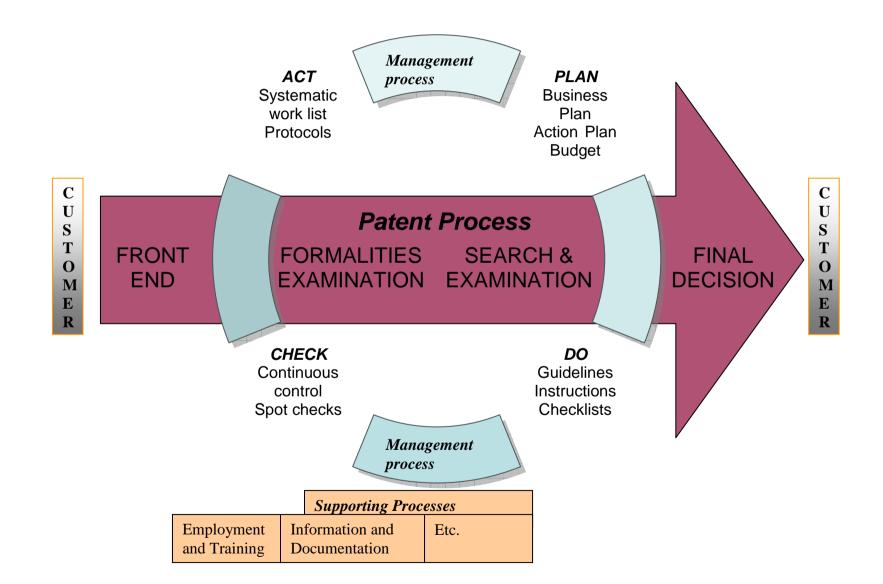
(This information is solely for the use as reference to the PCT Chapter 21 report of the Swedish Patent and Registration Office to the WIPO)

The Quality management system of the patent department has two parts;

The first being the Process oriented part. This part describes the organisation in form of processes where the main questions to be asked is; What is done and how do we do it? The goal of the patent process is to get satisfied customers in form of applicants, commercial and industrial life and society.

The second part describes the organisation in form of responsibility where the main question is; who does what?

Both parts are equally important of our quality management system and we work continuously on improving them.



# **Quality Management System and Process Orientation**

The Swedish Patent and Registration Office have a Quality Management System based on a process oriented approach. The main process is the process handling patent applications – the *Patent Process*. Supporting the *Patent Process* is the *Management Process* and *Supporting Processes*. The main objective of the Patent Process is a Satisfied Customer. The Management and supporting processes have as main objectives to serve the patent process and there by the customers.

# Patent process (Managed by process owner)

The Patent Process starts and ends with the customer. All other structures within the system has as the only goal to support this process and to make it run as smoothly as possible in order to get satisfied customers.

# Management process (Managed by head of patent department)

The management process roughly contains the following headings:

Plan

Business plan Action Plan Budget

Planning tools

Goals Vision

**Balanced Scorecard** 

Do

Relates back to patent process but supports the process with management tools such as benefits/salary program, group orientation, creativity making etc.

Check

Customer feedback

Quality assurance and quality control of process and product

Follow up on targets and goals

Spot checks Feedback

Act

Change processes and planning?

Action lists Protocols

Support processes

Recruiting and training

Information and documentation

Etc.

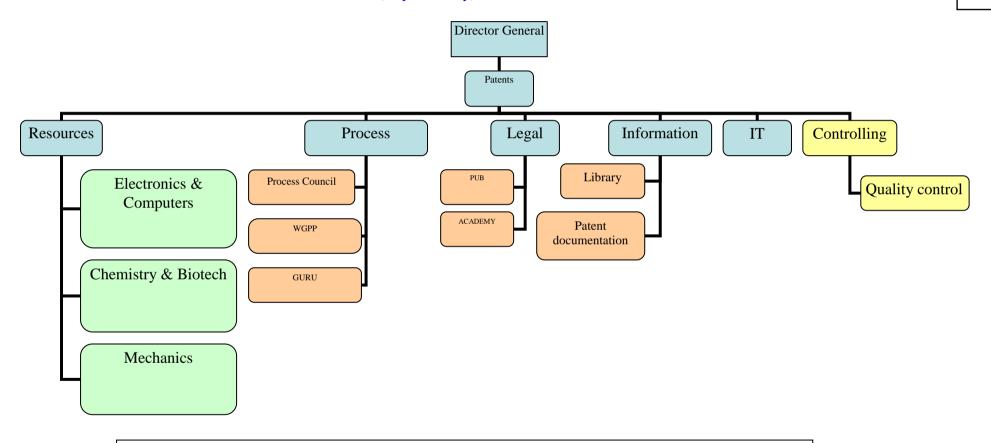
#### **Customers**

Meetings with the customers serve as input for the customers' demands on the patent process. They also serve as feedback input, if the agreed and initiated changes have been successful or not. Participants are representatives from organisations representing inventors, SME, industry and patent attorneys. The meetings are held every quarter of the year. Common issues for discussions are our services and the quality in the output from the patent process. Even major changes in the patent world and international patent legislation and its impact on the patent procedure are subjects for discussion at these meetings.

The SPRO has mainly the following channels established to generate feedback from our customers:

- Customer meetings (see above)
- Customer meetings in special technical fields (chemistry, so far)
- Surveys on performance in services and quality (every second year)
- Visits to customers

# Hierarchical organization (responsibility)



This organisational chart is focused on representing the organisation from a PCT view and therefore does not represent the whole SPRO organisation.

The Patent department has the responsibility divided in six areas:

**Resources:** Roughly, the responsibility of the Resource owner covers:

- Personnel including competence
- Production
- Time limits

has a total of 150 examiners, divided into 3 divisions: Mechanics, Electricity and Chemistry. Each division is divided into 3-4 directorates and each directorate is divided into technical groups.

#### **Process:**

The responsibility of the Process owner covers:

- Working processes and routines
- Quality of products and process
- Customers

#### Process council

Members of the Process council are the Process owner, chairman of the Patent process group and a lawyer. Here are most of the decisions taken concerning implementations of new routines in the patent process which can have been initiated from discussions at Customer meetings, from the production line or elsewhere.

# WGPP (Working group for patent process)

This working group is run under the Process council's command. The results of decisions concerning investigations and implementations of new routines as well as working procedures are in many cases dealt with in this group.

# GURU – tool group

Guru is a working-group consisting of examiners with specialist knowledge in search strategies as well as in deployment of new search tool and IT-support for the search/examination- procedure. For example they have deployed templates with standard clauses in Windows Word for reports. They are also doing a lot of programming of rex-preparations for search tools which mainly consist of EPOQUENET and commercial databases.

# Legal

#### **PUB**

PUB is a working group of experienced examiners with special knowledge of patent practice. Their tasks are mainly to update and implement new guidelines for search and examination and surveillance of the patent practice in appeal/supreme courts. Regarding the PCT-regulations, we have them in our own publishing tool in order to establish links from other IT-tools. We also have our own internal guidelines for PCT, which mainly relate to the administration of PCT application within the office.

# Academy

The academy is responsible for the training program of new as well as experienced examiners. We have produced an educational program, consisting of the different possibilities for personal education for examiners in patent related functions.

# **Information**

# Library services

Our in-house library supports the examiners in retrieving special documents which are not easily accessible. They assist with questions regarding publication date for Internet citations etc.

Patent documentation

The section for Patent documentation is responsible for the updating of our internal documentation databases and the scanning of application files into our internal Phoenix system.

# IT

The IT section is run by an IT-director; all IT services are internally purchased of an independent IT department

# **Controlling**

The controlling function is responsible for controlling of the system including economy and quality. The function works as an internal independent body directly under the head of patents. The controlling function has three main operating areas:

Financials Control
Quality Control
Patent statistics and planning tools