

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*

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Documents referred to in this report:

1) Organisation

Process oriented organisation

Process chart

Explanations

Hierarchical organisation (responsibility)

Organogram

Explanations

INTRODUCTION (PARAGRAPHS 21.01–21.02)

PRV has been an ISO 9001:2000 Certified Authority since October 2007. Our Quality Management System covers all parts of our business where the roles of RO, ISA and IPEA are central.

An important part of the system is to describe our organisation with a process oriented view, in order to focus the quality system on our processes and products as complements to our hierarchical organisation based on area of responsibility. See appendix.

QUALITY MANAGEMENT SYSTEM (PARAGRAPHS 21.03–21.09)

Establishment and maintenance of QMS (Paragraph 21.03)

The QMS of SPRO covers all parts of our business and has been ISO 9001 certified since 2007. The QMS pays specific attention to fulfilling the requirements required to underpin search and examination.

The QMS incorporates several quality assurance schemes as well as external reviews, in order to monitor compliance with these basic requirements and with PCT/GL/ISPE as well as the ISO 9001 standard.

Resources - infrastructure (Paragraph 21.05)

a)

The SPRO has a total of 163 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 qualification requirements. The minimum requirement is a Master of Science degree or equivalent and proven skills of search and examination within certain technical areas.

A computer-based monitoring system concerning demand, combined with productivity algorithms, identifies resources needed in different technical groups or directorates at any 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. A computer-supported system allows for detailed resource forecasting, including algorithms for adjusting to any different individual resource profile (age, sick leave, experience, skill, etc.). The systems are used together to simulate different scenarios of maximum and minimum resources needed to match the inflow of work.

ii)

Employment requirements (minimum Master of Science or equivalent) guarantee the technical and language qualifications of one individual to search and examine within the technical field of at least one technical group. A profile of personality and character is tested by our human resource division.

Search and examination staff pass through an internal educational programme including several steps of examination. The educational programme includes training from a tutor, also ensuring the skills of technical area, search and examination. An individual competence plan is renewed every year in order to see that technical competence remains at a satisfactory level.

iii) Search and examination staff are recruited with language skills according to the PCT regulations. Individual training programmes help to keep language skills updated. If necessary, additional language training at university level is provided. Staff are also supported by computer-based translation tools and, if necessary, the option of using external translation experts. The SPRO also tries to increase the number of languages covered to exceed the PCT regulations.

b) Formalities personnel

The technically skilled staff are 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 organisation (such 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 harmonisation.

d) Minimum documentation

The SPRO possesses or has access to a vast amount of documentation, which 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 necessary 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 specialised groups for both the search and the examination procedures.

f) Training and development programme

Examiners and Formalities staff take part in an effective initial training and development programme. 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 programmes support the in-house training. Refresher and update 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 educational programmes, in consultation with the individual, concerning both Intellectual Property Law and technical aspects. The educational programmes include: workshops (in-house), examiner exchange, in-house/ external seminars and courses. An extensive cross search/examining programme has been developed to ensure continuity and quality.

Patent experts are trained within a special expert programme attended by highly qualified examiners. The programme is extensive and runs over several years combined with normal search and examination duties. The programme ends with an examination and oral presentation of an examination thesis.

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))

(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)

- a) PCT quality checks
 - i. Second pair of eyes quality review in accordance with computer-based quality control software. The check is done for 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 and external audits, and monitored by a quality controller to assess conformity with ISO 9001 as well as Chapter 21. (Our Quality assurance procedures deal with the patent process and our end products.) Recording, measurement, monitoring and analysis is done with the aid of several different computer-based systems including: Customer feedback tools ensuring that customer feedback is properly handled, and Non-Conformity tools for detecting non-conformities and ensuring that processes are changed so that the same non-conformity will not arise twice.

- c)
 - i. Deficiencies of products i.e. S&E work are corrected prior to expedition, when detected by the quality checks.
 - ii. All deficiencies are reported into the non-conformities tool. A specialised process group (see appendix) considers the possible causes and the parts of the process in need of development in order to eliminate and prevent the deficiencies or that they recur. All considerations and the follow-up scheme are recorded in the non-conformities tool.

- d) The process group and the process council, lead by the process owner, have as their 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)

- a)
The result from the quality checks is analysed and communicated internally as well as at customer meetings.

- i) Deficiencies of S&E work are corrected immediately after identification together with feedback to the examiner. In case of interpretation difficulties, a patent expert or the legal section is involved to explain the underlying causes.
- ii) Information about corrective actions implemented by the process group is always given on the intranet and specialised information is given to concerned parties. The non-conformities tool records all deficiencies for all staff to see what they are and how they are corrected.
- 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)

(a) Applicant and examiner

In invitations and notifications, the name of the examiner is given as well as the telephone number, fax number and visitors' address to the Office. In Written Opinions and reports the name of the examiner and the telephone number to the office are given. The email address to the Office can be found on our website. Examiners are encouraged to contact the applicant by email or phone in order to promptly clarify any ambiguities.

(b) Guidance and information for users

The customer service centre answers questions of a 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 email. Extensive information and guidance, as well as specific information about the customer service centre, are available on our website.

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

On our website, 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 website and more specifically to the PCT website.

(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 about the handling of applications and the performance of the work done within the Office are handled by our Process owner (see

organisation in appendix). All complaints are dealt with 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 and preventions of all deficiencies in response to users are handled and communicated by the Process owner.

INTERNAL REVIEW (PARAGRAPHS 21.10–21.15)

Required Arrangements for Internal Review (Paragraph 21.10)

Internal Review

Internal Review is carried out by externally trained auditors, no auditor reviews within their own area of profession. Reviews are carried out according to a review scheme addressing different parts/ processes of the organisation at different times. All reviews are reported to the Quality manager and presented to top management at management reviews.

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

External review takes place twice a year and is carried out by an accredited quality auditor. Results are presented to top level management at management reviews.

OPTIONAL INFORMATION UNDER PARAGRAPH 21.17

Guide to Internal Review Arrangements (Paragraphs 21.11–21.15)

All Non conformities detected by internal, external or other procedures are registered in the computer based non conformities tool. This tool assigns the non conformity to the proper process owner. The tool includes means for saving plans of action, follow up etc. Internal Review always includes thorough follow up on reported non conformities.

[End of report]