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Patent Cooperation Treaty (PCT)

Common Quality Framework for International Search and Preliminary Examination

INITIAL REPORT ON QUALITY MANAGEMENT SYSTEMS

prepared by Swedish Patent and Registration Office (PRV)
(Changes marked in red)

The Authority should provide general background information relevant to the quality management system (QMS) as set forth in this template.

The descriptions below each main heading of this template should be considered examples of the type and arrangement of information that should be included under each heading. Each Authority may provide additional information beyond that set forth in this template as desired.

INTRODUCTION (PARAGRAPHS 21.01 - 21.03)

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

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

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

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

Normative reference for QMS: ISO 9001:2015, EQS. The Swedish Patent Office is compliant with all parts of ISO9001:2015 and EQS. As for section 7 of EQS the independent review mechanism consists of our external review partner engaged for review of our QMS according to ISO 9001. External Review partners are engaged on a three-year basis. The Swedish Patent

Office recertified its QMS according to the Standard ISO9001:2015 on 2019-09-09 – 2019-09-10 and 2019-09-12 – 2019-09-13, without deviations. PRV's quality management system is fully digitized and is available on the intranet.

1. LEADERSHIP AND POLICY

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

- (a) The quality policy established by top management.
- (b) The roles and names of those bodies and individuals responsible for the QMS, as specified by top management.
- (c) An organizational chart showing all those bodies and individuals responsible for the QMS.

- a) PRV quality policy is established by top management and published on the internal web PRVision, under the menu “management and control”. The policy covers PRV's quality objectives and commitment to comply with applicable requirements. The quality objectives include the results and values that the agency's business processes will deliver for customers, stakeholders and Swedish government.
 - b) PRV provides a service statement to our users, on our external web www.prv.se. The statement includes definitions regarding: timeliness, legal certainty, costs and quality on our services.
- a) Top management is responsible for quality management and quality management system according to ISO 9001: 2015. The Executive Management team has delegated the role as Director Quality Manager (DQM) to Gunnel Altin. DQM is responsible for ensuring that the quality management system has a high functionality for the purpose of all processes for intellectual property rights, for PRV to comply with:
- Customer requirements as well as requirements in regulations on the products and services offered,
 - The organization's own requirements
 - The goal of continuing to increase customer satisfaction.

The director quality manager heads a group of representatives from the processes for intellectual property rights and from the support processes. This group, called the quality council, is presented on the internal web, PRVision.

PRV has appointed internal quality auditors. The auditors, on behalf of Top Management and Director Quality Management, will systematically and independently, three times a year and as needed, conduct internal quality audits for information on improvements in the PRV quality management system, according to ISO 9001: 2015. Quality audit aims to provide information on how PRV can improve processes and activities for increased value creation based on management's quality policy, strategy and governance. Internal Audit identifies also deviations for measures.

The Director Quality Management is responsible of the internal review group as well as contacts with external ISO auditor.

The Director Quality Management and the quality council acts as support to management on all levels to ensure the proper function of the QMS. However, all directors and managers are responsible for running the business according to the QMS. The CFO Chef Financial Officer, is

responsible of strategic and planning issues regarding quality in the Executive Management team.

The body responsible for the QMS, and the names of its members responsible for implementing the QMS, are presented on the internal web. Delegates to the Internal Audit are also featured on the PRV intranet.

c)



The image above describes the tasks and processes of PRV, and how quality management involves unified processes for high delivery capabilities.

21.05 Indicate (e.g. by means of a table) the extent of compatibility between the Authority's QMS and the requirements of Chapter 21 of these International Search and Preliminary Examination Guidelines. Alternatively, indicate where the Authority is not yet compliant with these requirements).

[Sample table, to be amended as necessary]

Chapter 21 requirement				Extent of compliance		
				full	part	no
21.04		(a)	Quality policy available	✓		
		(b)	Identified roles and names for QMS responsibility	✓		
		(c)	Organizational chart available	✓		
21.05			Established compatibility of QMS with Chapter 21	✓		
21.06		(a)	Mechanisms to ensure effectiveness of the QMS	✓		
		(b)	Control of the continual improvement process	✓		
21.07		(a)	Communication of management about this standard to staff	✓		
		(b)	The PCT Guidelines are in line with the Authority's QMS	✓		
21.08		(a)	Management reviews take place	✓		
		(b)	Quality objectives are reviewed	✓		
		(c)	Communication of quality objectives to the relevant staff at the Authority	✓		
21.09		(a)	Performance of a yearly internal review of the QMS in/to	✓		
		(b)	determine the extent to which the QMS is aligned with Chapter 21	✓		
			determine the extent to which S&E complies with PCT Guidelines	✓		
		(c)	an objective and transparent way	✓		
		(d)	using input incl. information according paragraph 21.24	✓		
		(e)	recording the results	✓		
21.10			Risk and opportunities are addressed that can affect the QMS and the conformity of search and examination	✓		
21.13			Arrangements for establishing risk-based practices to	✓		
	(i)	(a)	understand issues that affect its ability to achieve intended results of the QMS	✓		
		(b)	understand the needs and expectations of interested parties	✓		
	(ii)		identify risks and opportunities related to the performance of the QMS as a basis for planning	✓		
	(iii)		plan and implement actions to address risks and opportunities	✓		
	(iv)		check the effectiveness of the actions taken	✓		
	(v)		continuously update risks and opportunities.	✓		
21.15			Assurance to monitor and adapt to actual workload	✓		

Chapter 21 requirement			Extent of compliance		
			full	part	no
	(i)	Infrastructure in place to ensure that a quantity of staff	✓		
		(a) sufficient to deal with the inflow of work	✓		
		(b) which maintains technical qualifications to S&E in all technical fields	✓		
		(c) which maintains the language facilities to understand languages according to Rule 34	✓		
	(ii)	Infrastructure to provide a quantity of skilled administrative staff	✓		
		(a) at a level to support the technically qualified staff	✓		
		(b) for the documentation of records	✓		
	(iii)	Ensuring appropriate equipment to carry out S&E	✓		
	(iv)	Ensuring documentation according to Rule 34	✓		
	(v)	(a) Instructions to help staff understand and act according to the quality criteria and standards	✓		
		(b) Instructions to follow work procedures accurately and they are kept up-to-date.	✓		
	(vi)	(a) Training and development program to ensure and maintain necessary skills in search and examination	✓		
		(b) Training and development program to ensure awareness of staff to comply with the quality criteria and standards.	✓		
	(vii)	(a) System in place for monitoring resources required to deal with demand	✓		
		(b) System in place for monitoring resources required to comply with the quality standards in S&E	✓		
21.16	(i)	Control mechanisms to ensure timely issue of S&E reports	✓		
	(ii)	Control mech. regarding fluctuations in demand and backlog	✓		
21.17	(i)	Internal quality assurance system for self-assessment	✓		
		(a) for compliance with S&E Guidelines	✓		
		(b) for channeling feedback to staff	✓		
	(ii)	System for measurement of data and reporting for continuous improvement	✓		
	(iii)	System for verifying the effectiveness of actions taken to correct deficient S&E work, eliminate the causes and prevent issues from recurring	✓		
21.19		(a) Contact person helping identify best practice between Authorities	✓		

Chapter 21 requirement				Extent of compliance		
				full	part	no
		(b)	Contact person fostering continual improvement	✓		
		(c)	Contact person providing for effective communication with other Authorities for feedback and evaluation	✓		
21.20	(i)	(a)	Appropriate system for handling complaints	✓		
		(b)	Appropriate system for taking preventive/corrective actions	✓		
		(c)	Appropriate system for offering feedback to users	✓		
	(ii)	(a)	A procedure for monitoring user satisfaction & perception	✓		
		(b)	A procedure for ensuring their legitimate needs and expectations are met	✓		
	(iii)		Clear and concise guidance on the S&E process for the user	✓		
			Indication where and how the Authority makes its quality objectives publicly available	✓		
21.21			Established communication with WIPO and designated and elected Offices	✓		
21.22			QMS of Authority clearly described and documented	✓		
21.23		(a)	Material making up the reference of quality procedures and processes for staff and management has been prepared and distributed	✓		
		(b)	Media available to support the reference material	✓		
		(c)	Document control measures are taken	✓		
21.24			Items which should be documented in the reference of quality procedures and processes	✓		
	(i)		Quality policy of the Authority and commitment to QMS	✓		
	(ii)		Scope of QMS	✓		
	(iii)		✓	✓		
	(iv)		the documented processes are carried out in the Authority	✓		
	(v)		Resources available to carry out processes and implementing the procedures	✓		
	(vi)		a description of the interaction between the processes and the procedures of the QMS.	✓		
21.25	(i)		Records which documents are kept and where they are kept	✓		
	(ii)		Records of results of management review	✓		
	(iii)		Records about training, skills and experience of staff	✓		
	(iv)		Evidence of conformity of processes	✓		
	(v)		Results of reviews of requirements relating to products	✓		

Chapter 21 requirement				Extent of compliance		
				full	part	no
	(vi)		Records of the S&E process carried out on each application	✓		
	(vii)		Record of data allowing individual work to be tracked	✓		
	(viii)		Record of QMS audits	✓		
	(ix)		Records on actions taken re. non-conforming products	✓		
	(x)		Records on actions taken re. corrective actions	✓		
	(xi)		Records on actions taken re. preventive actions	✓		
	(xii)		Records referring to search process documentation	✓		
21.26	(i)		Recording of the databases consulted during search	✓		
	(ii)		Recording of keywords, combination of words and truncations during search	✓		
	(iii)		Recording of the languages used during search	✓		
	(iv)		Recording of classes and combinations thereof consulted during search	✓		
	(v)		Recording of a listing of all search statements used in databases consulted	✓		
	(vi)		Records about other information relevant to the search	✓		
	(vii)		Records about limitation of search and its justification	✓		
	(viii)		Records about lack of clarity of the claims	✓		
	(ix)		Records about lack of unity	✓		
21.27			Report on its own internal review processes	✓		
21.28-21.30			Additional information on further inputs to its internal reviews	✓		
21.31			Initial report called for by paragraph 21.31	✓		

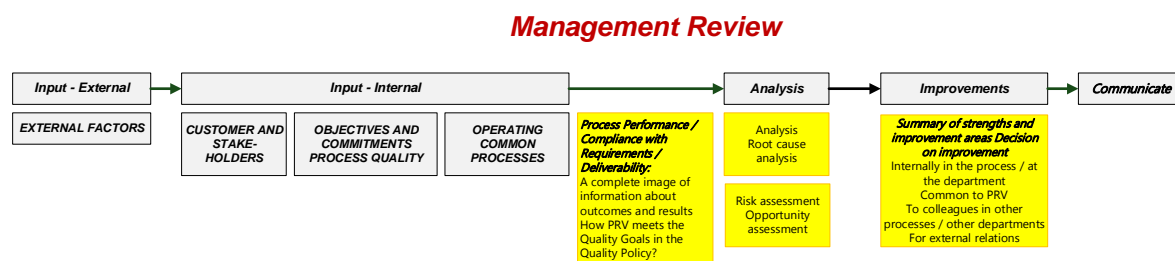
21.06 Indicate with reference to the organizational chart those bodies and mechanisms management uses to ensure:

- (a) the effectiveness of the QMS; and
- (b) that the process of continual improvement progresses.

a) The effectiveness of the QMS is ensured **twice a year for the PRV's departments and once a year by the entire authority**, by Management reviews as stated in ISO 9001:2015, requirement 9 "Evaluation and performance" and ISO requirement 10 "Improvements". The Executive Management team ensures the effectiveness of each process covered by the QMS by a follow up scheme, including the evaluation of each process ability to deliver the quality of service as stated in the service commitment. **The authority's ability to deliver is measured against Quality Policy and goals.**

b) The progress of continual improvement is ensured at the management reviews. The management reviews are conducted at least twice a year by top management and monthly by the management of the Patent department.

Topics for the management reviews include results from the following inputs (see list below). During the review, these results are analyzed to monitor the delivery capability of PRV. In case of deviations, risk assessment is carried out. Strengths are defined and decisions are made about improvements to the quality management system.



Input - External

EXTERNAL FACTORS

- Laws and constitutional amendments
- New Ownership Requirements
- Collaborators, other authorities
- External suppliers' performance
- International input
- International cooperation: EPO, WIPO
- Baltic cooperation
- WIPO website
- Neighboring countries

Input - Internal

CUSTOMER AND STAKEHOLDERS

Customer satisfaction:

- Follow-up of customers' and stakeholders' input
- Deviations
- Satisfied customer index
- Discontent and complaint

Stakeholder satisfaction:

- Partners (in the innovation system, ex authorities)
- Competitors who did not apply for patents but were affected
- 3-party operators

Owner Comments:

- Prospects of delivery regarding assignments and requirements

Input - internally

OBJECTIVES AND COMMITMENTS PROCESS QUALITY

Quality objectives:

- Legal certainty
- Correctly applied guidelines
- Clear and transparent decisions, understood and accepted by all (including competitors)
- Service commitments
- Process improvements
- Deviations, non-conformities
- Risks and opportunities
- Result and effect of actions taken after the last "Management review"
- Clear and transparent information and guidance from PRV
- Revision
- Compliance with value base
- Extended government assignments

Input - internally

OPERATING COMMON PROCESSES

Support processes

- Economy
- Resource utilization: time, skills
- Technical Support
- Project and development
- Agreement, cooperation with suppliers
- Deviations, governmental support, collected
- Working method: team work / cross-functional work
- Union input

To ensure effectiveness of our QMS we have "Quality audit", the body responsible for the QMS. Further, the process owner is responsible for developing and improving processes. Moreover, we conduct management reviews of the QMS system five times per year. We also have our internal web where the QMS-system is documented, and includes tools for management of deviations, suggestions, customer complaints and follow-up and control and continuous improvement of our processes and products with the help of the Deming-wheel (PDCA). To ensure progress of the continual improvement process we set goals for handling deviations, suggestions and complaints and for the output from our processes. The result is followed up during monthly top management meetings, documented on the web, and dealt with a PDCA-approach.

21.07 Indicate how management of the Authority communicates to its staff the importance of meeting treaty and regulatory requirements including:

- (a) those of this standard; and*
- (b) complying with the Authority's QMS.*

a) The importance of meeting treaty and regulatory requirements of PCT Ch 21 is communicated by patent experts, directors and our legal section. The communication is normally oral but, in some cases, complemented by intranet news flashes or similar.

b) The communication on complying with the authorities QMS is done by designated quality representatives as well as directors/management.

21.08 Indicate how and when top management of the Authority or delegated officers:

- (a) conducts management reviews and ensures the availability of appropriate resources;*
- (b) reviews quality objectives; and*
- (c) ensures that the quality objectives are communicated and understood by the relevant staff at the respective Authority.*

a) Management reviews are conducted twice a year by the Executive Management team and monthly by the management of the Patent department.

b) Quality objectives are reviewed frequently (weekly) at management meetings, the effectiveness of actions taken are evaluated at the management reviews.

c) Quality objectives are communicated weekly by management meeting protocols and by examiner meetings.

Top management conducts reviews **during meetings twice a month**. The meetings include follow up of resource availability and quality objectives. The quality objectives are communicated within the Authority through staff meetings (bilateral with manager or senior examiner/expert or in plenum), **by Quality Manager**, and on the internal web.

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

- (a) at least once per year (cf. paragraph 21.27);*
- (b) in accordance with the minimum scope of such reviews as set out in Section 8, namely:
to determine the extent to which the QMS is based on Chapter 21 (cf. paragraphs 21.27, 21.29(i));
to determine the extent to which Search and Examination work complies with PCT Guidelines (cf. paragraphs 21.27, 21.29(i));*
- (c) in an objective and transparent way (cf. paragraph 21.27);*
- (d) using input including information according to paragraphs 21.29 (ii)-(vi);*
- (e) recording the results (cf. paragraph 21.30).*

a) Internal review is performed by delegated officers on different processes and organizational parts at least once a year.

b) Reviews of patent processes or patent related functions shall always determine to what extent the QMS comply with all other rules and regulations for example; PCT Ch.21

Reviews of patent processes or patent related functions shall always include determination of compliance with all available rules and regulations i.e. Search and Examination work compliant with PCT Guidelines.

c) Delegated officers are externally trained to perform objective and transparent reviews. At least one officer per review has no connection to the reviewed function / process.

d) Input to reviews by delegated officers include information on corrective and preventive actions taken to eliminate cause of non-compliance, follow up actions from previous reviews, the effectiveness of the QMS itself and the process reviewed, feedback from customers and recommendations for improvement.

e) Results from internal reviews are recorded by:

- a) Internal review reports – fully accessible to all on intranet.
- b) Non-conformities are addressed in our non-conformities database.
- c) Customer input is addressed in customer input database.
- d) Suggestions for improvement addressed in improvement database.

Results from internal reviews serve as input to management reviews as well as external reviews.

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

Risk- and opportunity-based thinking enables the organization to identify factors that may cause its processes or its quality management system to deviate from or reach planned results. It also makes it possible to introduce preventative and reinforcing measures to minimize adverse effects on delivery capacity. and to make maximum use of opportunities when they arise.

Risk- and opportunity-based thinking:

- Identify factors that may cause processes or their quality management system to deviate from planned results
- Ensure that preventive measures are taken to eliminate possible deviations
- Identify strengths in the organization as well as other opportunities that can contribute to improved results. Distribute working methods that lead to better results.

Constantly meeting requirements and meeting future needs and expectations is a challenge for every organization in an increasingly dynamic and complex environment.

Risk and opportunities are addressed at the intranet under several headings, especially in the sections describing PRV's PDCA process. For example, under the "plan" heading, there is a link to a tool for risk and opportunities analysis.

2. RISK-BASED PRACTICES

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

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

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

21.13 Arrangements for establishing risk-based practices

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

- (i) (a) understand issues that affect its ability to achieve intended results of the QMS, and
(b) understand the needs and expectations of interested parties;*
- (ii) identify risks and opportunities related to the performance of the QMS as a basis for planning;*
- (iii) plan and implement actions to address risks and opportunities;*
- (iv) check the effectiveness of the actions taken; and*
- (v) continuously update risks and opportunities.*

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

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

The processes are designed based on the needs of customers and stakeholders. The delivery of results in the core processes is evaluated continuously. Process work with continuous improvements is carried out in accordance with the PDCA, and includes handling customer views, deviations and suggestions. Risk- and opportunity analysis is a part of this work.

3. RESOURCES

21.15 Explanatory note: The granting of ISA/IPEA status means that the Authority has demonstrated it has the infrastructure and resources to support the search and examination process. Chapter 21 calls for assurance that the Authority can continually support this process while accommodating changes in workload and meeting QMS requirements. The responses below, should provide this assurance.

Human resources:

(i) Provide information about the infrastructure in place to ensure that a quantity of staff: sufficient to deal with the inflow of work;

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

which maintains the language facilities to understand at least those languages in which the minimum documentation referred to in Rule 34 is written or is translated

is maintained and adapted to changes in workload.

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

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

for the documentation of records.

It is important to declare that the QMS of the Swedish patent office is based on a purely process oriented view. The process owner is responsible of the process infrastructure and overall function of the process. The management of the Patent Department is responsible for assuring the quantity and the ability of resources.

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 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.

Examiners in technical groups have influence on production planning and are expected to give prompt feedback to management in case of indications of forthcoming workload issues.

Employment requirements guarantee technical and language qualifications necessary for search and examination within at least one technical field. A trial period of 6 months is applied for all employees. Search and examination staff passes through an 18 month internal education program including several examinations. In order to ensure that technical qualifications are maintained, an individual competence plan is used and evaluated on a yearly basis. Further training is documented and evaluated.

A Patent expert program is conducted on regular basis. Examiners with exceptional skills in search and examination are selected to enter the program. The program is 3 years and ends with a written examination and the oral presentation of an advanced level thesis.

Search and examination staff have language skills according to PCT regulations. The individual competence plan includes language updates if necessary. Staff is supported by computer

based translation tools and in-house language experts. If necessary, there is an option of using external translation experts.

ii) The Formalities directorate as well as the Legal section support the technically qualified staff and facilitate the search and examination process. The infrastructure in place to ensure that the quantity of staff adapted to changes in workload is mainly based on Patent Department management meetings where managers from the technical directorates, the formalities directorate and the legal section discuss resource issues.

Technically qualified staff supports the formalities directorate on a regular basis to ensure smooth operation and to ensure process optimization.

Material resources:

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

(iv) Describe the infrastructure in place to ensure that at least the minimum documentation referred to in Rule 34 is available, accessible, properly arranged and maintained for search and examination purposes. State whether it is on paper, in microform or stored on electronic media, and where.

(v) Describe how instructions:

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

to follow work procedures accurately and consistently

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

iii) Support processes and functions are in place to support the search and examination process. An In-house IT function is responsible for IT soft- and hardware. The IT function is separated from the organization and a supplier-purchaser relationship is used to handle ordering and delivery conditions. The process owner acts as the purchaser for the Patent department. All internal IT systems are fostered by specially dedicated system administrators.

iv) The PRV has access to a vast amount of documentation that exceeds the minimum requirements set by the PCT and the Regulations. Most of the documentation is either stored electronically or can be accessed online. The PRV has a separate library and documentation section responsible for monitoring and updating documentation. (EPOQUE-net, Docdb:EPO)

v) All instructions;

As to help staff understand and adhere to quality criteria and standards as well as to follow work procedures accurately and consistently;

are documented and provided to staff on the intranet. The instructions are presented in a process oriented view that gives staff an overview of what instructions are applicable at all parts of the process. The different instructions are evaluated on a continuous basis by different expert and cross referential groups. Any changes to instructions are documented and news flashed.

Training resources:

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

acquire and maintain the necessary experience and skills; and

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

vi) Examiners and Formalities staff take part in an effective initial training and development program.

Newly recruited examiners follow an 18 month training program which includes theoretic parts and tutorial work. During this period the examiner is under the guidance of a tutor, who is responsible for the results of the examiner. There are two examination parts included in the program as well as an evaluation of the work concluding efficiency and quality before nomination to become a patent examiner.

Detailed written training material and online training programs 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 programs, in consultation with the individual, concerning both Intellectual Property Law and technical aspects. The educational programs may include: workshops (in-house), examiner exchange, cross search/examining, inhouse/ external seminars and courses.

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

All staff are informed of the importance of complying with the quality criteria and standards as a part of the introduction to PRV course when they start their employment. The quality manager has a main responsibility to ensure that this knowledge is maintained, this is done by yearly quality information meetings.

Also, there are practice discussions at meetings, quality checks, patent experts and search specialists that can be consulted in every technical field.

Oversight over resources:

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

to deal with demand; and

comply with the quality standards for search and examination.

vii) For long term (more than a year forward) the demand is predicted from monitoring and interpreting previous demand. Also, knowledge of the current and predicted state of the market is combined with statistical analysis (Holtz-Winther), to predict demand. The required resources are thereafter calculated with knowledge of previous production capacity using well-known macroscopic algorithms. On a shorter term the demand can be more precisely monitored by viewing actual demand values based on application databases. Also, the resources are more precisely calculated by using the same algorithms as for long term production estimation but with more accuracy. A specific in-house computer program is used by the directors to calculate and match demand and resources on a technical field level.

The system for continuously monitoring and identifying resources required complying with quality standards for search and examination is closely linked with the system for monitoring demand as described above. When we have enough resources to deal with demand this is a prerequisite to comply with quality standards. However, PRV closely monitors changes and input regarding to quality standards. Resources needed to deal with quality issues i.e. training or measures that slows down production, these resources are input to the system.

4. MANAGEMENT OF ADMINISTRATIVE WORKLOAD

21.16 Indicate how the following practices and procedures for handling search and examination requests and performing related functions such as data-entry and classification are implemented:

- (i) Effective control mechanisms regarding timely issue of search and examination reports to a quality standard as set by the respective Authority; and*
- (ii) Appropriate control mechanisms regarding fluctuations in demand and backlog management.*

i) All search and examination requests are monitored by each director, using an alert system with internal time limits set one month prior to PCT time limits. Lists of requests and their internal time limit are presented on individual, group and directorate level. Priority data is displayed 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.

ii) Demand and backlog data is monitored and controlled by a separate controlling and statistics function, at individual/technical group level.

5. QUALITY ASSURANCE

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

- (i) An internal quality assurance system for self-assessment, involving verification, validation and monitoring of searches and examination work:
for compliance with these Search and Examination Guidelines;
for channeling feedback to staff.*
- (ii) A system of measurement and collection of data and reporting. Show how the Authority uses the system to ensure the continuous improvement of the established processes.*
- (iii) A system for verifying the effectiveness of actions taken to correct deficient S&E work, eliminate the causes, and to prevent issues from recurring.*

i) For all applications a quality control is made by another examiner according to a computer based checklist, including check of search and examination guidelines. ("Second pair of eyes") The checklist provides information if the second examiner agrees disagrees or has doubts within a certain number of checked fields. The information is stored for statistical data and feedback. However, the examiners and in some cases a patent expert always meet and analyze the results before any written communication is forwarded.

As a part of quality assurance procedures, the "patent expert board" suggests and carries out yearly spot checks of the patent process.

Patent experts and the patent expert board provide feedback to staff both on individual applications and on statistical analyses on the results of the quality control.

ii) As described above data from quality checks in all application is stored and analyzed to provide feedback and continuous improvement of the patent process. All non-conformities and suggestions are also separately analyzed and form input to patent experts and staff on quality issues as to always improve the process.

iii) Non-conformities are always fed into a separate system that has functionality to force the elimination of causes and to prevent deficient work to recur.

6. COMMUNICATION

Inter-Authority communication:

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

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

21.19 Provide the name, job title and contact details of the Authorities designated quality contact person who will take responsibility for:

- (a) *helping identify and disseminate best practice among Authorities;*
- (b) *fostering continual improvement; and*
- (c) *providing for effective communication with other Authorities to allow for prompt feedback from them so that potential systemic issues can be evaluated and addressed.*

Quality Contact person:

Gunnel Altin
gunnel.altin@prv.se
+46 (0) 8 782 28 30

Communication and guidance to users:

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

- (i) *An appropriate system for handling complaints and making corrections; taking corrective and/or preventative action where appropriate; and offering feedback to users.*
- (ii) *A procedure for: monitoring user satisfaction and perception; and for ensuring their legitimate needs and expectations are met.*
- (iii) *Clear, concise and comprehensive guidance and information to users (particularly unrepresented applicants) on the search and examination process, giving details of where it is to be found e.g. link to Authority's web site, guidance literature.*

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

i) General complaints on PRV concerning customer relations, fees, opening hours etc. is handled by our IT based customer feedback system. All complaints concerning the handling of applications and the performance of the work done within the patent process are handled by our Process owner. All complaints are carefully documented, and an investigation is carried out in all cases. The investigation is performed by the board of patent experts; the result is delivered

to the process owner who communicates with the client. Corrections are made by the responsible examiner.

If preventive action is needed, the Process Owner will set up a plan of action and the effectiveness of this plan will be checked at a later stage.

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 PRV has made an obvious mistake, we can refund fees.

ii) Measurement of user satisfaction and perception is done by recurrent customer surveys, performed by a Swedish authority (SCB), every third year. PRV also document and measure any customer feedback from our customer feedback system. All feedback from customers is feed in to this system either by the customer, **through** a feedback form on our website, or inputted to the systems by any employee according to specific instructions on customer feedback administration. PRV also holds customer meetings with representatives from industry, attorneys and inventors several times every year.

Our management system includes targets for realized customer suggestions.

Note that PRV mainly receives customer feedback via the customer feedback system, through PRV's customer support and through meetings with customers and stakeholders.

iii) PRV issues guidance booklets on the application, search and examination procedures. See also www.prv.se.

There are informative pages on the website on how to file a patent application as well as information of the patent process. Filers not using an attorney receive information with each action PRV makes. They also receive a welcoming letter with general information upon filing.

iv) See service commitments: <http://www.prv.se/en/About-us/Vision-and-mission/Service-commitments/>

21.21 Communication with WIPO and designated and elected Offices:

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

PRV uses the EDI system for most of the communication with WIPO concerning applications. All feedback from WIPO, normally mail or email, is forwarded to the PCT administrative group, and immediately evaluated and addressed. In case of Legal aspects the feedback is forwarded to the Legal section. The Legal section also has several contacts within WIPO as to easily clarify and address any feedback.

7. DOCUMENTATION

21.22 Explanatory note: The QMS of the Authority needs to be clearly described and implemented so that all processes in the Authority and the resulting products and services can be monitored, controlled, and checked for conformity. This is done by documenting the procedures and processes affecting the quality of work as a reference for staff and management at the Authority (see paragraph 21.23).

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

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

For the purposes of this report indicate:

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

PRV Quality Manual.

PRV applies ISO 9001: 2015, quality management, which facilitates management/control of the authority's processes for legal and qualitative results for customers and stakeholders. PDCA is the PRV's control model; we plan, design strategies, implement them and follow up and improve processes and working methods for best results. Risks and opportunities are identified, and improvements are being made.

PRV's quality management system is fully digitized on the intranet, PRVision. There is information about PRV's environment, management, core processes and support processes as well as working methods with instructions, routines and managers.

The **operation** quality Manuals of PRV is document, called "**Working instructions, with routines**", to be found on our intranet, **available for all**. It consists of numerous links to the actual parts of our Intranet where the actual processes and procedures are described. Below is a brief description of the Manual and its contents. When tagged with "link", the headline has equivalence in one of our main links on the intranet (placed at the top menu)

a)

PRVs Business an overview

A brief description of PRVs business and assigned tasks.

Words and Phrases

Explanations of words and phrases in the manual

Main Processes

Explanation of PRVs main processes and how we use processes for describing our business

Start – link

Explanation on how you can personalize the start page of PRVs intranet.

News – link

Explanation on the news area on the intranet

Organization - link

Explanations concerning PRVs organization and organization chart, including responsibility and authority.

Management - link

- Economic

Explains the process of economic management

- Strategic

Explains the process of Strategic management (3-5 years)

- Operative

Explains the process of operational management (0-1 year)

VSAA-How we do it - link

- Processes

Design Processes

Patent Processes

National Process

PCT Process – description

o Laws and Rules

o Guidelines

- Search and Examination Guidelines(WIPO Pdf)

o Working instructions

o Examiners work area

- Electronic memo card

- Quality control notes

- Language and electronic translators

o Classification

o Flowcharts

o Manuals

o Glossary/Index

Support - link

Explains our support processes

My employment – link

Explains what kind of information is presented concerning employment i.e. salary, vacation etc.

ISO 9001

Relates our quality management system to the ISO 9001:2015 requirements.

b) Intranet

c) Advanced document control in the intranet platform keeps track of any changes and presents version numbering and indication on latest version etc.

21.24 Indicate whether the material making up the reference of quality procedures and processes include the following:

- (i) the quality policy of the Authority including a clear statement of commitment to the QMS from top management;
- (ii) the scope of the QMS, including details of and justification for any exclusions;
- (iii) the organizational structure of the Authority and the responsibilities of each of its departments;
- (iv) the documented processes carried out in the Authority such as receipt of incoming applications, classification, distribution, search, examination, publication and support processes, and procedures established for the QMS, or references to them;
- (v) the resources available for carrying out the processes and implementing the procedures; and
- (vi) a description of the interaction between the processes and the procedures of the QMS.

- i) Yes
- ii) Yes
- iii) Yes
- iv) Yes
- v) Yes
- vi) Yes

21.25 Indicate which types of records the Authority maintains, such as:

- (i) a definition of which documents are kept and where they are kept;
- (ii) results of management review;
- (iii) training, skills and experience of personnel;
- (iv) evidence of conformity of processes, resulting products and services in terms of quality standards;
- (v) results of reviews of requirements relating to products;
- (vi) the search and examination processes carried out on each application;
- (vii) data allowing individual work to be tracked and traced;
- (viii) records of QMS audits;
- (ix) actions taken re. non-conforming products, e.g. examples of corrections;
- (x) actions taken re. corrective action;
- (xi) actions taken re. preventative action; and
- (xii) search process documentation as set out in Section 7.

- i) Yes, Intranet, Quality Manual
- ii) Yes, Intranet, Management process
- iii) Yes, Intranet, Management process, Patent process
- v) Yes, Intranet, Internal reviews
- vi) Yes, Intranet, Patent process, Application data support.
- vii) Yes, Intranet, Application data support
- viii) Yes, Intranet, Management process
- ix) Yes, Intranet, separate system for non-conformities, Olivia
- x) Yes, Intranet, separate system for non-conformities, Olivia

- xi) Yes, Intranet, separate system for non-conformities, Olivia
- xii) Yes, Intranet, search process documentation system

8. SEARCH PROCESS DOCUMENTATION

21.26 *For internal purposes the Authority should document its search process.*

The Authority should indicate

(a) *which of the following are included in this record:*

- (i) *the databases consulted (patent and non patent literature);*
- (ii) *the keywords, combinations of words and truncations used;*
- (iii) *the language(s) in which the search was carried out;*
- (iv) *the classes and class combinations searched, at least according to the IPC or equivalent;*
- (v) *a listing of all search statements used in the databases consulted.*

(b) *which other information relevant to the search itself is included in this record e.g. a statement of the subject of search; details of special relevance to internet searching; a record of documents viewed; on-line thesaurus, synonym or concept databases, etc.*

(Explanatory note: The IA is requested to list other information it may collect to monitor and improve the search process)

(c) *which special cases are documented and whether records are kept denoting any:*

- (vi) *limitation of search and its justification*
- (vii) *lack of clarity of the claims; and*
- (viii) *lack of unity.*

a)

- i) Yes
- ii) Yes
- iii) Yes
- iv) Yes

v) Search statements are partly listed if relevant to search results; full search history recording is available but not used.

b) Se appended print screens from PRV documentation tools.

c) Se appended print screens from PRV documentation tools.

9. INTERNAL REVIEW

21.27 Explanatory note: The Authority should report on its own internal review arrangements. These reviews determine the extent to which it has established a QMS based on the model of Chapter 21 and the extent to which it is complying with the QMS requirements and the Search and Examination Guidelines. The reviews should be objective and transparent to demonstrate whether or not those requirements and guidelines are being applied consistently and effectively and should be undertaken at least once a year. With reference to point 21.08 of this template, the Authority may provide additional information on its internal review arrangements under this section if it so wishes.

21.28-21.30 These arrangements are reported according to this template in Section 1, above, at points 21.04 - 21.09. The Authority may provide additional information on further inputs to its internal reviews under this section, if it so wishes.

Reviews are frequently conducted by delegated officers, see point 21.09.

10. ARRANGEMENTS FOR AUTHORITIES TO REPORT TO THE MIA

21.31 There are two stages in the reporting arrangements outlined in Chapter 21: the initial report called for by paragraph 21.31(a), and supplementary annual reports in accordance with paragraph 21.31(b). At the second informal meeting of the Quality Subgroup in Canberra on February 6 and 7, 2012, the Subgroup recommended that, instead of submitting full reports every five years and cumulative updates in the intervening years, Authorities should submit each report in the form of a full report, making the differences from the previous year's report clear, for example using "track changes" or other form of highlighting. The template for the supplementary annual reports is therefore no longer used.

Appendix: Memo Card and Quality control software:

Memo Card

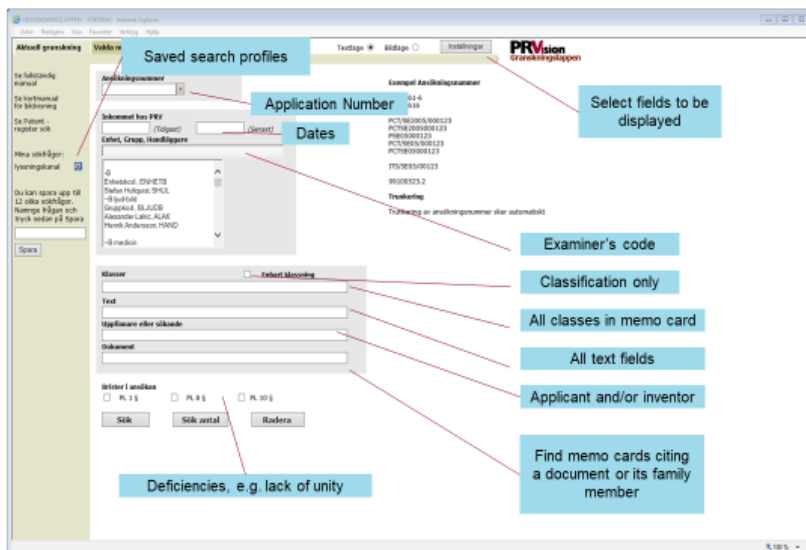
The screenshot shows a software interface for a Memo Card. The interface is divided into several sections:

- Drawer:** A label pointing to the top navigation bar.
- Toggle between layout for text or drawing:** A label pointing to a button in the top right corner.
- Navigation bar:** A label pointing to the left sidebar.
- Drawing from Phoenix:** A label pointing to a technical drawing on the right side.
- Click to open insert window:** A label pointing to a button in the left sidebar.
- Bibliographic info from internal databases:** A label pointing to a table of bibliographic information.
- To be filled in by the examiner:** A label pointing to a section of the drawing.

The main content area displays a table with the following data:

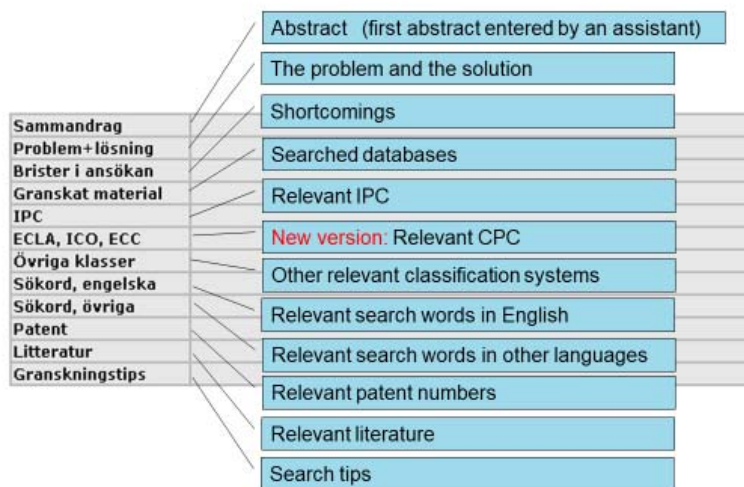
Publikationsnummer	877000129
Ansökningsdatum	1993-06-10
Utgivningsdatum	1994-12-10
Uppfinnare	Inger Inverniz, Uppfinnare SE
Sökord	Skär, Projektion, Låg, Låg, 45, Skåp, Höjd, 1
Skötsel	DP, AB, 234 50, Örebro

The search window



PRV

To be filled in by the examiner



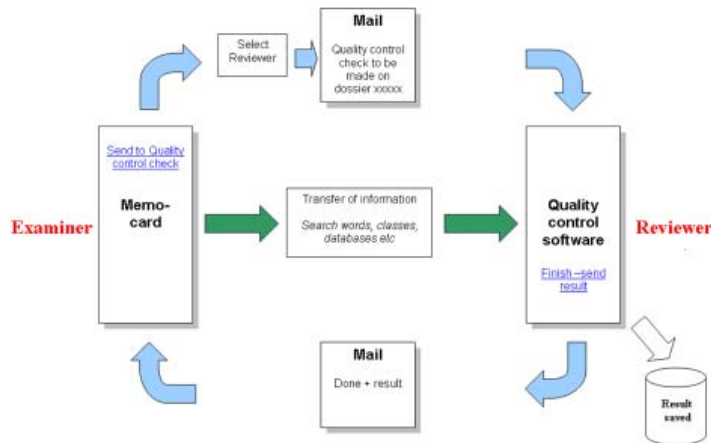
PRV

Final memo-card

The screenshot shows a software interface for a 'Final memo-card'. On the left, there is a form with fields for 'Aktuellt givningsslag', 'Vårdsnummer (CT)', 'Sida', 'Rör till resultat', 'Arbets tillstånd', 'Ny utskick', 'Spärrnummer', 'Sticks till utskick', 'Staps till CT', 'FRIKÄTT', and 'KÖLIDÅRS'. A blue box with the text 'Send memo-card to quality check control' is overlaid on the form. On the right, there is a technical diagram of a 'Glazed facade' showing 'Reflective coating' and 'Pivotable' components. The diagram includes labels for 'Glazed facade', 'Reflective coating', and 'Pivotable'.

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Memo Card



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Quality Control Software

**G=satisfactory
T=questionable
O=unsatisfactory**

Blue text: Information transferred from memo card.

Green text: Evaluation of written opinion

**New version – two levels
E=agreed
D=discussion**

PRV

Quality Control Software

**G=satisfactory
T=questionable
O=unsatisfactory**

Has the application been correctly classified?

Have shortcomings in the application been commented on?

Has relevant material been searched?

Have the documents been correctly categorized?

Evaluation of the written opinion
*Has novelty been correctly used?
 Have problem-solution been correctly used?
 Have all the claims been considered?
 Have other shortcomings been commented on?
 Style*

**New version – two levels
E=agreed
D=discussion**

PRV

[End of document]

[End of document]