PATENT COOPERATION TREATY (PCT)

Common Quality Framework for International Search and Preliminary Examination

INITIAL REPORT ON QUALITY MANAGEMENT SYSTEMS

prepared by the Finnish Patent and Registration Office (PRH)

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

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

INTRODUCTION (PARAGRAPHS 21.01 - 21.03)

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

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

Each authority should then provide at least the information indicated in the descriptive boxes, under the following headings

The quality management system (QMS) of the Patents and Innovation Line (PAI) of the Finnish Patent and Registration Office (PRH) has been established according to ISO 9000 standard series.

The PAI´s QMS is annually assessed by an independent and impartial certification body which conducts external audits. On the basis of ISO 9001, the auditor assesses the PAI's ability to meet the requirements established by customers, law, and the organisation itself. On 23 November 2006, Inspecta Certification, a member of IQNet, granted the PRH the first quality certificate as proof that the PAI´s QMS complies with the requirements of

standard SFS-EN ISO 9001:2000. On 4 November 2014, Inspecta Certification assessed QMS and decided to continue the validity of the certificate. The certificate confirms that the QMS complies with the requirements of the standard SFS-EN ISO 9001:2008. The certificate is valid for a three-year period and is monitored once a year. At the moment, the certification covers the processing of national patent applications, the processing of utility models, and the processing of international applications under the Patent Cooperation Treaty (PCT).

The "Standard for the European Quality Management System" (EQMS, CA/57/07) and the set of "Product Quality Standards" (PQS, CA/135/08) are regarded as basic requirements in the development of the processes of the PAI.

1. LEADERSHIP AND POLICY

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

   (a)   The quality policy established by top management.

   (b)   The roles and names of those bodies and individuals responsible for the QMS, as delegated by top management.

   (c)   An organisational chart showing all those bodies and individuals responsible for the QMS.

(a)…(c)

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

The PAI management group supervises the PAI's activities. It carries out quality reviews at least twice a year. In the reviews, the quality feedback from the previous review period is analysed, changes and improvements in the PAI's activities and quality management system are decided on, and the PAI's quality policy and quality objectives are revised.

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

The quality manager, who is a member of the management of the PAI, is in charge of the every-day implementation of the quality management system.

The mission, the vision and the values of the PRH and the PAI have been determined.

The operational and financial plan of the PRH presents the areas of focus and the economic data of the PRH for the period of four years. The operational and financial plan for the years of 2015–2018 presents the strategic lines of the PRH, which are based on the strategic lines of the state government and the strategies of the interest groups. The international institutions dealing with intellectual property rights are considered being of special importance and Finland as a member can influence their work and their goals.

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

Information to the staff is provided according to the PAI's information strategy.

The quality policy established by top management is available in the Quality Manual, as well as the roles and names of those bodies and individuals responsible for the QMS and the organisational chart (see Appendixes 1 and 2).

> *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)	Organisational chart available	✓		
21.05		Established compatibility of QMS with Chapter 21	✓		
21.06	(a)	Mechanisms to ensure effectiveness of the QMS	✓		
	(b)	Control of the continual improvement process	✓		
21.07	(a)	Communication of management about this standard to staff	✓		
	(b)	The PCT Guidelines are in line with the Authority's QMS	✓		
21.08	(a)	Management reviews take place	✓		
	(b)	Quality objectives are reviewed	✓		
	(c)	Communication of quality objectives throughout the Authority	✓		
21.09	(a)	Performance of a yearly internal review of the QMS in/to	✓		
	(b)	(i) determine the extent to which the QMS in based on Chapter 21	✓		
		(ii) determine the extent to which S&E complies with PCT Guidelines	✓		
	(c)	an objective and transparent way	✓		
	(d)	using input incl. information according paragraph 21.17	✓		
	(e)	recording the results	✓		
21.10		Assurance to monitor and adapt to actual workload	✓		
21.11	(a)	Infrastructure in place to ensure that a quantity of staff	✓		
		(i) sufficient to deal with the inflow of work	✓		
		(ii) which maintains tech. qualifications to S&E in all technical fields	✓		

Chapter 21 requirement			Extent of compliance		
			full	part	no
		(iii) which maintains the language facilities to understand languages according to Rule 34	✓		
	(b)	Infrastructure to provide a quantity of skilled administrative staff	✓		
		(i) at a level to support the technically qualified staff	✓		
		(ii) for the documentation records	✓		
21.12	(a)	(i) Ensuring appropriate equipment to carry out S&E	✓		
		(ii) Ensuring documentation accord. to Rule 34	✓		
	(b)	(i) Instructions to help staff understand and act accord. the quality criteria and standards	✓		
		(ii) Instructions to follow work procedures accurately and they are kept up-to-date.	✓		
21.13		(i) L&D program to ensure and maintain necessary skills in S&E	✓		
		(ii) L&D program to ensure awareness of staff to comply with the quality criteria and standards.	✓		
21.14	(a)	System in place for monitoring resources required to deal with demand	✓		
	(b)	System in place for monitoring resources required to comply with the quality standards in S&E	✓		
21.15	(a)	Control mechanisms to ensure timely issue of S&E reports	✓		
	(b)	Control mech. regarding fluctuations in demand and backlog	✓		
21.16	(a)	Internal quality assurance system for self assessment	✓		
		(i) for compliance with S&E Guidelines	✓		
		(ii) for channeling feedback to staff	✓		
	(b)	A system for measurement of data and reporting for continuous improvement	✓		
	(c)	System for verifying the effectiveness of actions taken to correct deficient S&E work	✓		
21.17	(a)	Contact person helping identify best practice between Authorities	✓		
	(b)	Contact person fostering continual improvement	✓		
	(c)	Contact person providing for effective comm. with other Authorities for feedback and evaluation	✓		
21.18	(a)	(i) Appropriate system for handling complaints	✓		

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

Chapter 21 requirement			Extent of compliance		
			full	part	no
	(k)	Records on actions taken re. preventive actions	✔		
	(l)	Records referring to search process documentation	✔		
21.24	(a)	(i) Recording of the databases consulted during search	✔		
		(ii) Recording of keywords, combination of words and truncations during search	✔		
		(iii) Recording of the languages used during search	✔		
		(iv) Recording of classes and combinations thereof consulted during search	✔		
	(b)	Records about other information relevant to the search	✔		
	(c)	(i) Records about limitation of search and its justification	✔		
		(ii) Records about lack of clarity of the claims	✔		
		(iii) Records about lack of unity	✔		
21.25		Report on its own internal review processes	✔		
21.26-21.28		Additional information on further inputs to its internal reviews	✔		
21.29		Initial report called for by paragraph 21.19	✔		

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

(a)   the effectiveness of the QMS; and

(b)   that the process of continual improvement progresses.

As indicated in the Quality Manual and the process charts:
(a)   the effectiveness of the QMS is ensured by the management of the PAI, the quality management group, the quality manager, the quality assessment group, the internal auditing, and the external auditing; and
(b)   the progress of the process of continual improvement is ensured by the management of the PAI, the quality management group, the quality manager, the internal auditing, the external auditing, the heads of the divisions, and the principal examiners.

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.

The management of the PAI communicates to its staff the importance of meeting treaty and regulatory requirements including
(a)   those of the standards of PCT; and
(b)   complying with the QMS of the PAI.

The information strategy of the PAI determines the principles of communication.

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

(a)   *conducts management reviews and ensures the availability of appropriate resources;*

(b)   *reviews quality objectives; and*

(c)   *ensures that the quality objectives are communicated and understood throughout the respective Authority.*

As indicated in the Quality Manual:
(a)   the top management conducts management reviews twice a year, and ensures the availability of appropriate resources;
(b)   in these reviews, the quality objectives are considered; and
(c)   the top management ensures that the quality objectives are communicated and understood throughout the respective Authority following the information strategy of the PAI.

21.09 *Indicate whether top management or delegated officers of the Authority perform an internal review of the QMS in accordance with paragraphs 21.25-21.28:*

(a)   *at least once per year (cf. paragraph 21.25);*

(b)   *in accordance with the minimum scope of such reviews as set out in Section 8, namely:*

(i)   *to determine the extent to which the QMS is based on Chapter 21 (cf. paragraphs 21.25, 21.27(a));*

(ii)   *to determine the extent to which Search and Examination work complies with PCT Guidelines (cf. paragraphs 21.25, 21.27(a));*

(c)   *in an objective and transparent way (cf. paragraph 21.25);*

(d)   *using input including information according to paragraphs 21.27 (b)-(f);*

(e)   *recording the results (cf. paragraph 21.28).*

(a)…(e)
Delegated officers of the PRH perform an internal review of the QMS once or twice per year, see Section 8.

2. Resources

21.10 Explanatory note: The granting of ISEA status means that the Authority has demonstrated it has the infrastructure and resources to support the search and examination process. Chapter 21 calls for assurance that the Authority can continually support this process while accommodating changes in workload and meeting QMS requirements. The responses to Sections 21.11 to 21.14, below, should provide this assurance.

21.11 Human resources:

(a) Provide information about the infrastructure in place to ensure that a quantity of staff:

> *(i) sufficient to deal with the inflow of work;*
>
> *(ii) which maintains the technical qualifications to search and examine in the required technical fields; and*
>
> *(iii) which maintains the language facilities to understand at least those languages in which the minimum documentation referred to in Rule 34 is written or is translated*
>
> *is maintained and adapted to changes in workload.*

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

> *(i) at a level to support the technically qualified staff and facilitate the search and examination process;*
>
> *(ii) for the documentation of records.*

(a) Management continuously monitors the performance outcome, number of applications, person-years, processing times, and backlogs. The resource management includes the following documents and recordings: grounds for calculating performance (pieces of work) and productivity; statistics and calculations by the head of the division in charge of resource follow-up; annual statistics from the performance and productivity system; monthly statistics for the number of applications; monthly statistics for pieces of work and working hours; quarterly reports on person-years, demand, and productivity; backlog lists; quarterly examiner follow-up reports (performance and targets); and schedules and documents for the PRH planning: the operational and financial plan, periodic planning year chart, and strategy year clock. Prognoses are made for the development in the number of applications, changes in activities and work practices, and the number of people leaving the PRH.

On the basis of the initial information and prognoses, the management estimates how many pieces of work are necessary in order to reach the processing time and quality objectives, and what are the pieces of work needed for clearing out backlogs. The estimated number of pieces of work and the proportion between these and person-years are used to calculate the person-years needed by each division. Employees are recruited on the basis of the calculations, estimates by the heads of the divisions, and financial aspects. All examiners must have a full university degree (doctor's degree is preferred) and good knowledge of several languages.

(b) The administration of the PRH is responsible of the planning, finances, human resources, international and legal affairs, communications, and data administration, to the extent those issues have not been delegated to the Lines or other units. At the PAI, the General unit and the PCT unit are responsible for the examination of the formal requirements of the national applications and the PCT applications, respectively. New employees get personal training, and complementary training is organised when necessary. Job descriptions define the tasks entrusted to each employee of the PRH. They also specify the qualifications required, i.e., which education, work experience, and skills are required for each position.

21.12 Material resources:

(a) Describe the infrastructure in place to ensure that

(i) appropriate equipment and facilities such as IT hardware and software to support the search and examination process are provided and maintained;

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

(b) Describe how instructions

(i) to help staff understand and adhere to the quality criteria and standards, and

(ii) to follow work procedures accurately and consistently

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

(a) The purpose of the IT services of the PRH is to meet the requirements and expectations specified in the service level agreement concerning the IT systems used by the PAI. The task of the IT services is to ensure a disturbance-free handling of applications, fluent searches and examinations, and reliable patent administration. The IT staff, the strategic co-operation partners of the PAI, and an active involvement in the European development of IT services within the EPO ensure that the PRH has at its disposal the resources required for providing the IT services. The Information Management of the PRH is in charge of the IT services.

The PRH has replaced its paper processing of PCT and patent applications with electronic processing and introduced the electronic document service for customers. The PRH has also started to pilot a new production control system for PCT and patent processes. The aim of the new system is to minimize the deviation of the response time for the applicant.

The Online working group and the library of the PRH ensure that the examiners have access to all necessary search documentation. The examiners have access to 103 databases through EPOQUE. The non-patent literature requirements of PCT search in each technical field have been analysed and an easy access to the documentation has been ensured.

(b) The Patent Manual includes the guidelines for the handling of national patent applications and utility model applications, and for conducting international novelty searches and international preliminary examinations of PCT applications. For every step in the handling process, the Patent Manual states the contents requirements and procedural guidelines, according to which the applications are handled by the PRH. The purpose of the guidelines is to advise the staff in charge of the handling of the applications in such a way that they are aware of the handling procedure and can independently apply the guidelines in different situations. The manual "Guidelines for the handling of patent applications" includes detailed instructions for how examiners shall carry out in practise the measures to be taken regarding the handling of national patent applications, utility model applications, and PCT applications. The guidelines also include general instructions concerning the work of the examiners. Other instructions have been gathered to the Intranet pages. These instructions include, for example, guidelines for examiners, IT guidelines, and guidelines for the classification of patent applications. The manuals and the instructions are updated regularly. The Patent Manual working group is responsible for updating the Patent Manual.

> *21.13 Training resources:*
>
> *Describe the training and development infrastructure and program which ensures that all staff involved in the search and examination process:*
>
> *(i)   acquire and maintain the necessary experience and skills; and*
>
> *(ii)   are fully aware of the importance of complying with the quality criteria and standards.*

A working group on training issues plans and organises the training of the examiners, and evaluates the efficiency of the training. New examiners are given training according to a qualification programme for examiners, and they become familiar with the work under the guidance of personal tutors. The staff maintains and develops their professional skills by taking part in courses on patent issues, IT, languages and technical special areas.

> *21.14 Oversight over resources:*
>
> *Describe the system in place for continuously monitoring and identifying the resources required:*
>
> *(a)   to deal with demand; and*
>
> *(b)   comply with the quality standards for search and examination*

See points 21.11 and 21.15.

3. Management of administrative workload

> *21.15 Indicate how the following practices and procedures for handling search and examination requests and performing related functions such as data-entry and classification are implemented:*
>
> *(a)   Effective control mechanisms regarding timely issue of search and examination reports to a quality standard as set by the respective Authority; and*
>
> *(b)   Appropriate control mechanisms regarding fluctuations in demand and backlog management.*

(a)…(b)

The processing times of applications in their various phases are monitored by a computerized administrative system. The real-time situation of the backlog can be accessed. The heads of the divisions and the principal examiners are aware of the work load in real time.

The PAI management group decides on the quality objectives, including the objectives for the processing times of applications in their various phases. The quality management group monitors the processing times, the backlogs, the outcome of the objectives, and the need to make improvements or changes in the processes.

The PAI management group monitors the outcome of the objectives on the basis of the results of management reviews.

4. Quality assurance

21.16   *The following are required quality assurance measures for timely issue of search and examination reports of a quality standard in accordance with the Guidelines. Indicate how the following are implemented:*

(a)   *An internal quality assurance system for self assessment, involving verification, validation and monitoring of searches and examination work:*

(i)   *for compliance with these Search and Examination Guidelines;*

(ii)   *for channelling feedback to staff.*

(b)   *A system of measurement and collection of data and reporting. Show how the Authority uses the system to ensure the continuous improvement of the established processes.*

(c)   *A system for verifying the effectiveness of actions taken to correct deficient S&E work, eliminate the causes, and to prevent issues from recurring.*

(a)…(c)

The bodies responsible for the QMS are presented in appendix 2.

Two examiners work in co-operation on the search of a PCT application: the searching examiner carries out an international novelty search and the verifying examiner checks the work done by the searching examiner. The verifying examiner uses a checklist as a part of his quality assurance. In addition, the principal examiners check all the decisions made for national patent applications.

The head of the division monitors daily the decisions and opinions given by examiners. He uses a checklist of the head of the division as a part of his quality assurance.

The working group on quality assessment is set to ensure the good quality of the searches, examinations, decisions, reports, and written opinions by examiners. The working group uses random sampling and annually checks at least two applications by each examiner. One of the applications should be a PCT application. On the basis of the decisions, reports, and opinions given by the examiner in the different steps of the handling process, the working group analyses whether the examiner has followed the set quality criteria, quality standards, and guidelines. The working group measures the quality level of searches and examinations by means of the criteria stated in the quality objectives. The working group determines a quality class of each application process based on the quality assessment criteria.

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

The quality management group assesses and develops the function of the quality management system and follows up the realisation of the quality objectives. If necessary, it makes changes and improvements to the processes, guidelines, training, and systems. It may also submit proposals to the PAI management group in order to revise the quality objectives. Further, the quality management group makes preparations for both management reviews and internal and external audits. The sources of information for the quality management group as a basis for decision-making include: performance and productivity statistics; processing times; reports from internal and external audits; reports from the working group on quality assessment; quality assessment reports from the heads of the divisions; customer feedback and customer satisfaction surveys.

5. Communication

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21.17 Inter-Authority communication:

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

(a)   helping identify and disseminate best practice among Authorities;

(b)   fostering continual improvement; and

(c)   providing for effective communication with other Authorities to allow for prompt feedback from them so that potential systemic issues can be evaluated and addressed.

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(a)…(c)
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21.18 Communication and guidance to users:

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

(a)   An appropriate system for

(i)   handling complaints and making corrections;

(ii)   taking corrective and/or preventative action where appropriate; and

(iii)   offering feedback to users.

(b)   A procedure for:

(i)   monitoring user satisfaction and perception; and

(ii)   for ensuring their legitimate needs and expectations are met.

(c)   Clear, concise and comprehensive guidance and information to users (particularly unrepresented applicants) on the search and examination process, giving details of where it is to be found e.g. link to Authority's web site, guidance literature.

(d)   An indication of where and how the Authority makes its quality objectives publicly available for the users.

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(a)…(d)
      The quality management group gathers, analyses, and uses the feedback concerning customer satisfaction. A customer complaint concerning the activities of the PAI is forwarded to that unit and official, to which the complaint is associated. Both complaints and responses given are forwarded to the quality manager. The handling of customer complaints within the PAI is described in detail in the instruction "Customer complaints".

      The information sources of customer feedback include: direct communication with customers, written feedback from customers on the handling of the searches and examinations of applications, feedback from the Contact committee, customer satisfactions surveys, annual autumn meetings with customers, and the appeals to the Board of Appeal

and to the Supreme Administrative Court. Direct communication includes customer contacts by phone or e-mail due to issued decisions and opinions, as well as informal discussions at training events, fairs, etc. Customers may provide feedback by mail, by e-mail or in electronic form through the website of the PRH. Feedback mail is first entered into the diary at the PatRek Customer Service. Then, it is forwarded to the management of the PRH and the quality manager, and, if necessary, to the unit concerned. The PAI receives customer feedback on the quality of searches and examinations through the Contact committee, which is an interactive forum between the PAI, patent agencies and corporate patent attorneys. The customer satisfaction target level and carrying out a customer satisfaction survey are agreed on in a result agreement between the Ministry of Employment and the Economy and the PRH. The Administration (Planning and development) of the PRH is responsible for surveys. The results of the surveys are analysed for each unit. The quality goals have been presented to the users in the Contact committee and in the annual autumn meetings.

A consulting service is available to customers. Guidance and information is available also on the websites of the PRH: http://www.prh.fi.

21.19 Communication with WIPO and designated and elected Offices:

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

The communication with WIPO is mainly provided via PCT-EDI and by e-mail and telephone. The WIPO feedback is evaluated and addressed by the PCT Section of the PRH and necessary amendments to the internal guidelines (for example detailed checklists) of the PCT Section are made. The PRH communicates rarely with designated and elected Offices.

6. Documentation

21.20 Explanatory note: The QMS of the Authority needs to be clearly described and implemented so that all processes in the Authority and the resulting products and services can be monitored, controlled, and checked for conformity. This is done in the documents that make up the Quality Manual of the Authority (see paragraph 21.21).

(Note: This point is informative. No response is required by the template to paragraph 21.20)

21.21 The documents that make up the Quality Manual serve to document the procedures and processes affecting the quality of work, such as classification, search, examination and related administrative work. In particular, the Quality Manual indicates where to find instructions on the procedures to be followed.

For the purposes of this report indicate:

(a)   the documents making up a Quality Manual that have been prepared and distributed;

(b)   the media on which it is supported (e.g. Internal Publication, Internet, Intranet); and

(c)   document control measures taken e.g. version numbering, access to latest version.

21.21…21.23

The documentation for the quality management system comprises: the Operations Manual (the Quality manual), quality policy, and quality objectives; the statutes and guidelines necessary in planning and actions; and documents and recordings required by the standards for quality management systems.

Both the Working Manual and the documents and recordings related to the quality management system are maintained and stored by means of the IMS program (IMS). They

are available to the persons authorised to view them. Other statutes and guidelines necessary in planning and actions are available via the data systems of the PRH (PAT-Intra, Innonet, Internet).

The updated version of the Working Manual approved by the quality manager including the date of approval can be viewed in the IMS Section Working Manual. The quality policy and quality objectives agreed on by the PAI management are presented in the Working Manual (Chapters 2 and 5). The most important statutes and guidelines and their addresses are listed at the end of this Manual (Chapter 9) as well as in the IMS Section Processes (phase descriptions).

The documents for the quality management system, such as procedural guidelines and agendas, have been recorded in the IMS Section Documents. Here, you can find the names of the persons who drew up, controlled, and approved each document, the number of the version, and the times for the measures. The documents include guidelines (Chapter 9 of the Working Manual), the documents relating to management, staff, resources, the IT services, and customer co-operation, the documents of the quality management group and the Working group on quality assessment, and agendas of meetings.

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

Detailed guidelines have been issued for the control of the documents and for the control of the quality management system recordings.

The archive plan of the PRH lists all documents received by the PRH due to its tasks and drawn up in connection with its activities, as well as the information most relevant to document management. Thus, the PAI documents also appear from the PRH's archive formation plan irrespective of the recording form, as well as the documents'
– subject matter (why it exists and what is the name of the creator)
– registration (in the diary, another register)
– filing manner,
– place of storage,
– time of storage,
– publicity: basis and time for concealment of non-public documents,
– the directories through which documents are found, and
– interrelationships between data and data contents.

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

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

21.22 *Indicate whether the documents making up the Quality Manual include the following:*

(a) *the quality policy of the Authority including a clear statement of commitment to the QMS from top management;*

(b) *the scope of the QMS, including details of and justification for any exclusions;*

(c) *the organizational structure of the Authority and the responsibilities of each of its departments;*

(d) *the documented processes carried out in the Authority such as receipt of incoming applications, classification, distribution, search, examination, publication and support processes, and procedures established for the QMS, or references to them;*

(e) *the resources available for carrying out the processes and implementing the procedures; and*

(f) *a description of the interaction between the processes and the procedures of the QMS.*

See previous point.

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

(a) *a definition of which documents are kept and where they are kept;*

(b) *results of management review;*

(c) *training, skills and experience of personnel;*

(d) *evidence of conformity of processes, resulting products and services in terms of quality standards;*

(e) *results of reviews of requirements relating to products;*

(f) *the search and examination processes carried out on each application;*

(g) *data allowing individual work to be tracked and traced;*

(h) *records of QMS audits;*

(i) *actions taken re. non-conforming products, e.g. examples of corrections;*

(j) *actions taken re. corrective action;*

(k) *actions taken re. preventative action; and*

(l) *search process documentation as set out in Section 7.*

See previous point.

7. Search process documentation

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

The Authority should indicate

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

      (i)   the databases consulted (patent and non patent literature);

      (ii)   the keywords, combinations of words and truncations used;

      (iii)   the language(s) in which the search was carried out;

      (iv)   the classes and class combinations searched, at least according to the IPC or equivalent;

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

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

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

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

      (i)   limitation of search and its justification

      (ii)   lack of clarity of the claims; and

      (iii)   lack of unity.

(a)   The examiner is obliged to fill in a search record form which contains:
   –   the databases consulted (patent and non patent literature);
   –   the keywords, combinations of words and truncations used;
   –   the language(s) in which the search was carried out;
   –   the classes and class combinations searched, according to the IPC, ECLA or equivalent; and
   –   a listing of all search statements used in the databases consulted.

(b)   The search record further includes:
   –   a statement of the subject of search;
   –   description of internet searching;
   –   annually searched documentation (e.g. books);
   –   consulted persons; and
   –   notes concerning clarity, unity, non-patentability or other special issues.

(c)   Special cases are documented and records are kept denoting, e.g.
   –   limitation of search and its justification;
   –   lack of clarity of the claims; and
   –   lack of unity.

8. Internal review

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

21.26-21.28   *These arrangements are reported according to this template in Section 1, above, at points 21.04 - 21.09. The Authority may provide additional information on further inputs to its internal reviews under this section, if it so wishes*

The PAI carries out internal audits at regular intervals in order to find out whether the quality management system meets applicable requirements and comes up to the plans, standards and the requirements set by the organisation itself, and whether the system is implemented and maintained in an effective way. Guidelines have been issued for the internal audit procedure. The guidelines describe how internal audits shall be planned, carried out, and reported on, and how corrective actions are controlled. The results of the internal audits are presented to the quality management group. This group analyses the results and makes changes and improvements to the processes, guidelines and training. The group may also make proposals to the PAI management group.

In addition to internal audits, the quality management system of the PAI is annually assessed by an independent and impartial certification body which conducts external audits.

9. Arrangements for Authorities to Report to the MIA

21.29   *There are two stages in the reporting arrangements. The document up to this point relates to the initial report called for by paragraph 21.29. It will be supplemented annually by further reports in accordance with paragraph 21.30.*

Appendix 1

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                    ┌──────────────────┐              ┌──────────────────┐
                    │   Patents and    │              │  External Audit  │
                    │ Innovations line │              └──────────────────┘
                    └──────────────────┘
                                    ┌──────────────────┐
                                    │ Management Group │
                                    └──────────────────┘

    ┌─────────────────┐   ┌──────────────────┐   ┌──────────────────┐
    │ Technical       │   │ Quality          │   │ Information       │
    │ Division 1      │   │ Management,      │   │ services         │
    │ Mechanical      │   │ Development and  │   └──────────────────┘
    │ Engineering     │   │ IT               │
    └─────────────────┘   └──────────────────┘   ┌──────────────────┐
                                                   │ Internal Audit   │
    ┌─────────────────┐                           └──────────────────┘
    │ Technical       │
    │ Division 2      │                           ┌──────────────────┐
    │ Construction and│                           │ Quality          │
    │ Process         │                           │ Administration   │
    │ Engineering     │                           └──────────────────┘
    └─────────────────┘
                                                   ┌──────────────────┐
    ┌─────────────────┐                           │ Quality          │
    │ Technical       │                           │ Management Group │
    │ Division 3.1    │                           └──────────────────┘
    │ Physics and     │
    │ Electrical      │                           ┌──────────────────┐
    │ Engineering     │                           │ Quality          │
    └─────────────────┘                           │ Assessment Group │
                                                   └──────────────────┘
    ┌─────────────────┐
    │ Technical       │                           ┌──────────────────┐
    │ Division 3.2    │                           │ Internal and     │
    │ Data Processing │                           │ External         │
    │ and ICT-        │                           │ IT-Services      │
    │ technology      │                           └──────────────────┘
    └─────────────────┘
                                                   ┌──────────────────┐
    ┌─────────────────┐                           │ Patent           │
    │ Technical       │                           │ Classification   │
    │ Division 4      │                           └──────────────────┘
    │ Chemical        │
    │ Engineering and │                           ┌──────────────────┐
    │ Biotechnology   │                           │ Training         │
    └─────────────────┘                           └──────────────────┘

    ┌─────────────────┐
    │ Legal Matters   │
    │ and Registration│
    └─────────────────┘

    ┌─────────────────┐
    │ PCT-Unit        │
    └─────────────────┘
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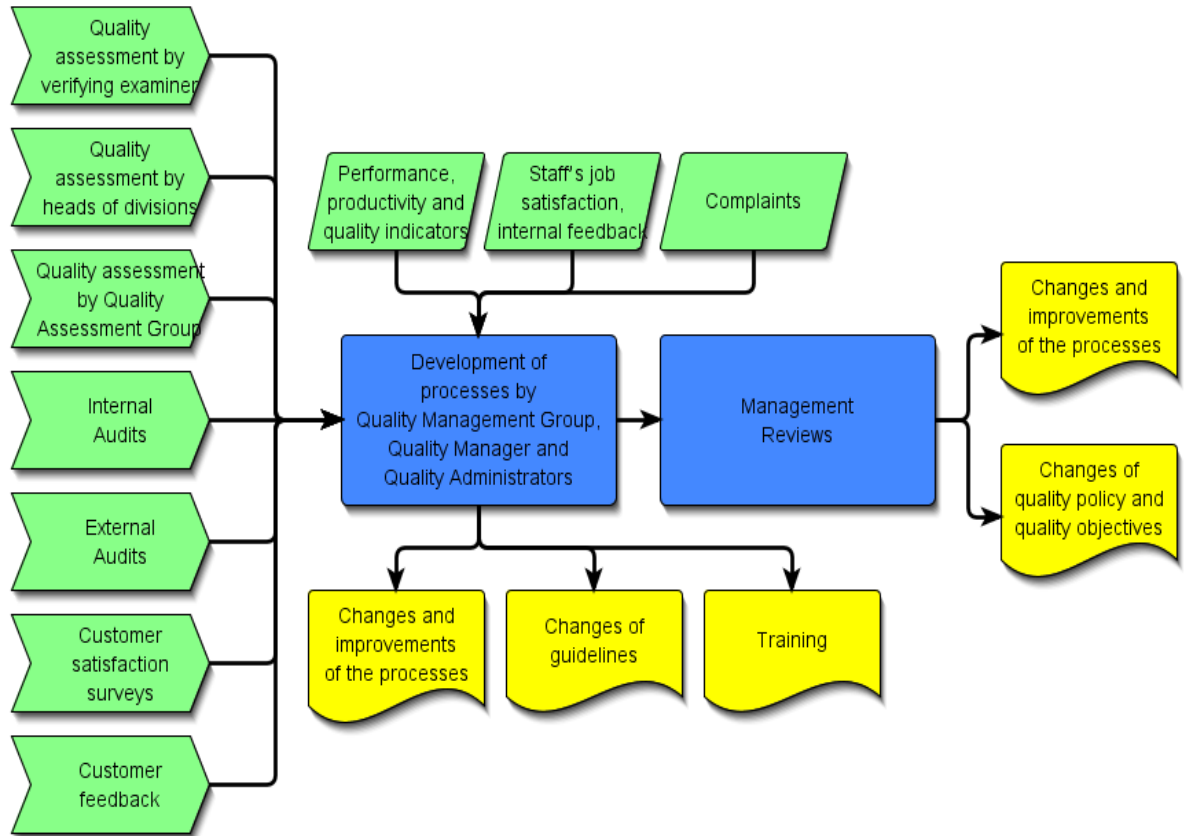
The organisational chart of the PAI of the PRH

Appendix 2

The bodies responsible for the QMS of the PAI of the PRH

[End of document]