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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 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)

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 of 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.

The Finnish Patent and Registration Office (PRH) has been acting as an International Searching Authority and an International Preliminary Examining Authority since 2005.

The Quality Management System (QMS) of the Patents and Trademarks (PTM) Division of the Finnish Patent and Registration Office (PRH) is established and maintained in accordance with ISO 9001:2015.

The QMS of the PTM is assessed annually by an independent and impartial certification body through external audits. In 2006, Inspecta Certification, a member of IQNet, granted the PRH its first quality certificate as evidence that its QMS complied with ISO 9001:2000. This initial certificate covered the processing of PCT applications in the roles of Receiving Office (RO), International Searching Authority (ISA), and International Preliminary Examining Authority (IPEA).

Since 2006, the scope of the QMS has been gradually expanded. Today, it covers all functions of the PTM, including the processing of national and international patent applications, utility models, trademarks, and industrial designs, as well as advisory and commercial search services.

The certificate confirms that the QMS meets the requirements of ISO 9001:2015. Each certificate is valid for a three-year period and is subject to annual monitoring.

Summary of changes in 2025

21.15 (iii), (iv). Front-office modernization. Preparations continued. The national patent filing system was deployed as planned. PCT filing system was launched in September 2025.

21.15 (vi). Lean training program. The Lean training program (2023–2025) was completed in spring 2025, supporting continual improvement capabilities.

21.17 (i)...(iii). In 2025, PRH and EPO continued the harmonization program for the purposes of harmonizing search activities between the offices. The subject matter of the harmonization applications were 'simulation and modelling inventions / neural network and training' and 'conciseness / non-unity in mechanics'.

21.19 (a)...(c). Governance and roles. Organizational changes in the patent area: Jani Päiväsaari moved to Director, PTM (Patents and Trademarks); Hanna Aho was appointed Patent Process Owner (with overall responsibility also for the PCT process); the Receiving Office (RO) Process Owner is Mika Kotala.

21.20 (ii). Complaint and nonconformity handling. The handling of internal nonconformities moved to an intranet electronic ticket form that automatically routes cases to the Authority's electronic case management system for processing, follow-up and reporting. External feedback and complaints submitted via the PRH website enter the same workflow, ensuring uniform handling, traceability and a full audit trail; the Quality Manager has visibility for monitoring and trend analysis.

21.23 (b). QMS documentation platform. The Quality Manual and all QMS documents and records were migrated from legacy IMS to the PTM Wiki (Confluence).

21.27. The external re-assessment audit was conducted by Eurofins Electric & Electronics Finland Oy in September 2025. The audit covered the full scope of the QMS of the PTM. No non-conformities were identified in the re-assessment.

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)–(c)

The Director of the PTM is responsible for the operations of the PTM. The Director oversees the strategy, financial balance, and activities of the PTM in order to achieve its strategic objectives, with particular emphasis on factors affecting quality.

The PTM Management Group supervises the PTM's activities and conducts management reviews at least twice a year. In these reviews, quality feedback from the previous period is analyzed, decisions are made on changes and improvements to the PTM's activities and quality management system, and the PTM's quality policy and quality objectives are updated.

The Patent Process Management Group evaluates and develops the functioning of the quality management system and monitors the achievement of quality objectives. When necessary, it proposes changes and improvements to processes, guidelines, training, and systems. It may also submit proposals to the PTM Management for revising the quality objectives. In addition, the Patent Process Management Group prepares material for both management reviews and internal and external audits.

The Quality Manager is responsible for the day-to-day implementation and continual improvement of the PTM's quality management system.

The mission, vision, and values of the PRH and the PTM have been defined.

The operational and financial plan of the PRH sets out the focus areas and economic data for a four-year period. It presents the strategic priorities of the PRH, which are based on the strategic lines of the government and the strategies of stakeholder groups. International institutions dealing with intellectual property rights are considered particularly important, and Finland, as a member, can influence their work and objectives.

Within the strategic framework of the PRH, a specific strategy has also been drawn up for the PTM. This strategy provides more detailed information on the measures implemented by the PTM to help the PRH achieve its strategic goals.

The quality policy established by top management is available in the Quality Manual, along with the roles and names of the bodies and individuals responsible for the QMS. An organizational chart of the PTM, showing all the bodies responsible for the QMS, is presented in Figure 1, while a schematic presentation of the interrelations between these bodies is shown in Figure 2.

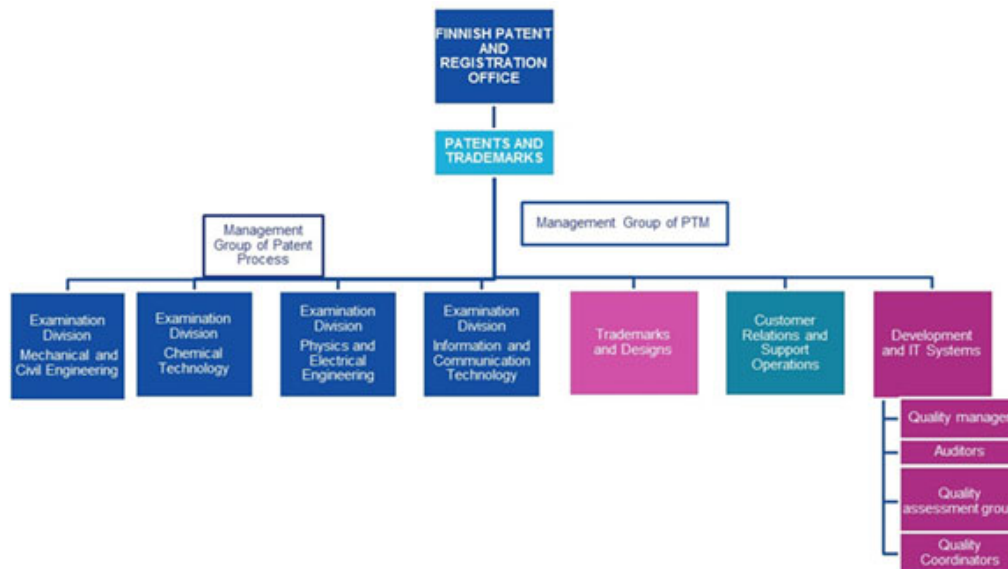


Fig 1. Organizational chart of the PTM showing the bodies responsible for the QMS.

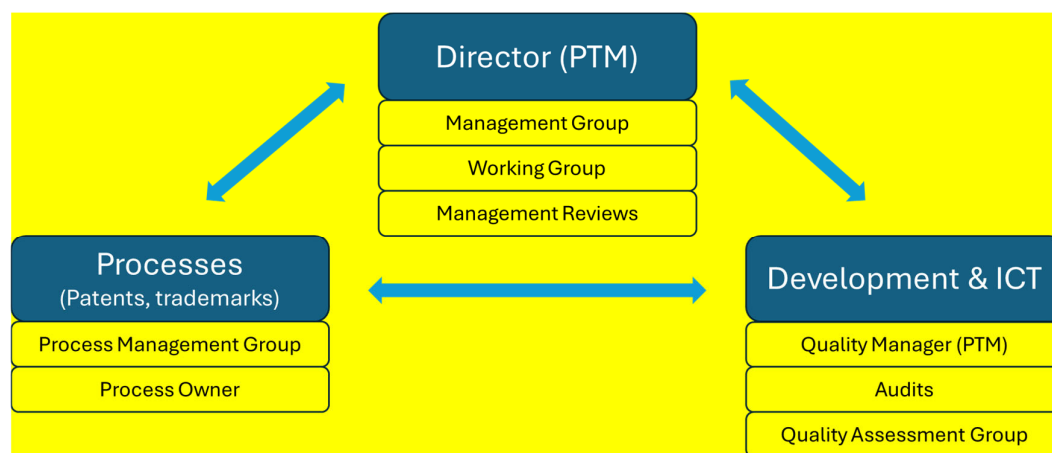


Fig 2. Schematic presentation of the interrelations between the bodies responsible for the QMS.

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).

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 search and examination (S&E) complies with PCT Guidelines	✓		
		(c)	an objective and transparent way	✓		

Chapter 21 requirement				Extent of compliance		
				full	part	no
		(d)	using input incl. information according to paragraph 21.29	✓		
		(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	✓		
	(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 search and examine in all technical fields	✓		
	(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	✓		

Chapter 21 requirement				Extent of compliance		
				full	part	no
		(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 mechanisms 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	✓		
		(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 and information on the search and examination process for the user	✓		
			Indication where and how the Authority makes its quality objectives publicly available	✓		
21.21		(a)	Established communication with the International Bureau	✓		
		(b)	Established communication with 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	✓		

Chapter 21 requirement			Extent of compliance		
			full	part	no
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)	Organizational structure and responsibilities	✓		
	(iv)	Documented processes carried out in the Authority	✓		
	(v)	Resources available to carry out processes and implementing the procedures	✓		
	(vi)	Description of the interaction between the processes and the procedures of the QMS.	✓		
21.25	(i)	Records of 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)	Records of evidence of conformity of processes, resulting products and services in terms of quality standards	✓		
	(v)	Records of results of reviews of requirements relating to products	✓		
	(vi)	Records of the S&E process carried out on each application	✓		
	(vii)	Records of data allowing individual work to be tracked	✓		
	(viii)	Records 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 limitation of search and its justification	✓		
	(vii)	Records about lack of clarity of the claims	✓		

Chapter 21 requirement				Extent of compliance		
				full	part	no
	(viii)		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.*

As indicated in the Quality Manual and the process charts:

- (a) the effectiveness of the QMS is ensured by the management of the PTM, the Patent Process Management Group, the Quality Manager, the Quality Assessment Group, as well as by internal and external audits (see also Fig. 2); and
- (b) the progress of continual improvement is ensured by the management of the PTM, the Patent Process Management Group, the Quality Manager, internal and external audits, the Heads of Divisions, and the Principal Examiners.

The flowchart illustrating the mechanisms for continual improvement is presented in Fig. 3.

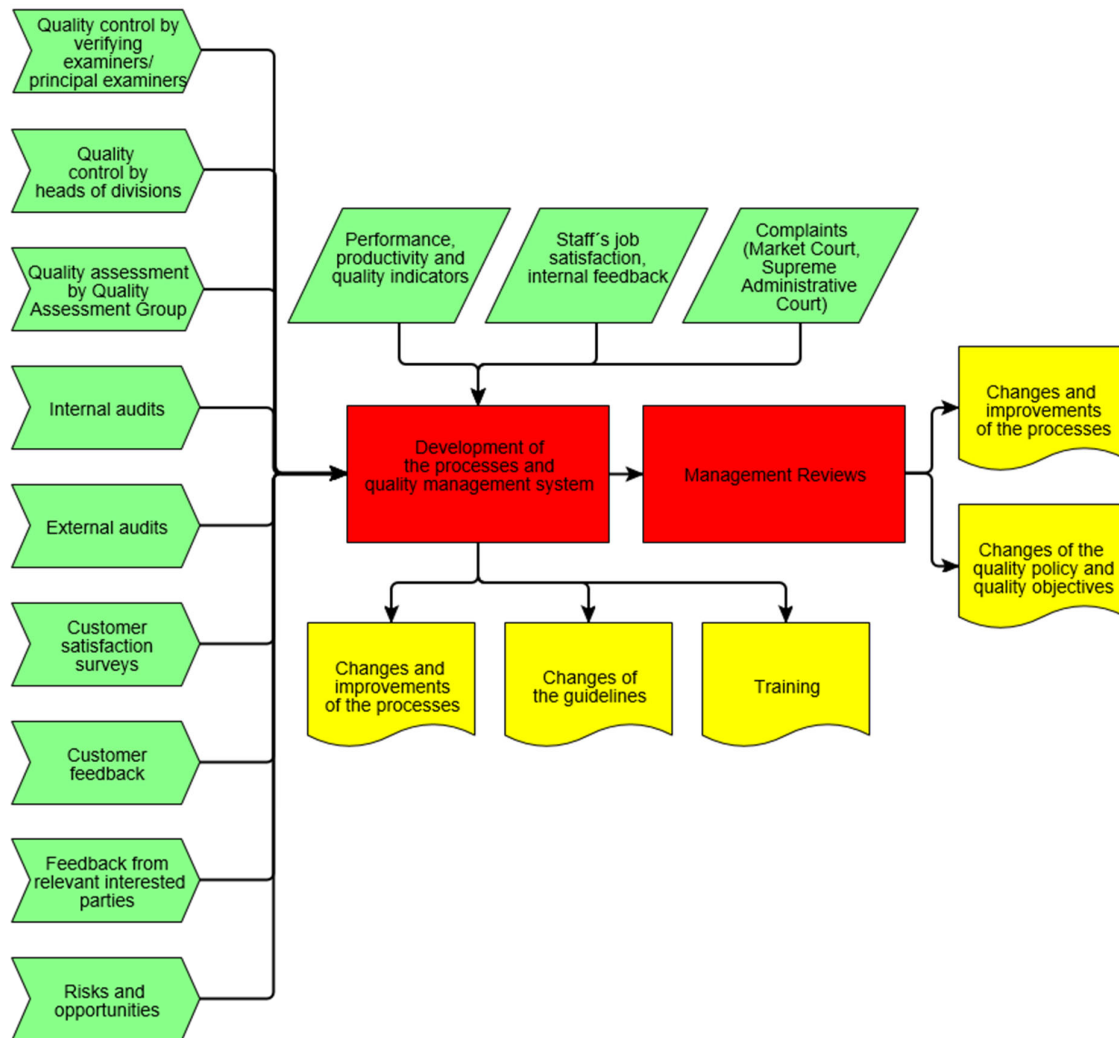


Fig 3. Flowchart relating to mechanisms of continual improvement.

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 PTM communicates to its staff the importance of meeting treaty and regulatory requirements primarily through meetings and training sessions. This includes:

- (a) compliance with the standards of the PCT; and
- (b) adherence to the QMS of the PTM.

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.

As indicated in the Quality Manual:

- (a) top management conducts management reviews twice a year and ensures the availability of appropriate resources;
- (b) quality objectives are reviewed during these meetings; and
- (c) top management ensures that the quality objectives are communicated and understood across the Authority in accordance with the PTM's information strategy.

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 9, 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)...(e)

Top management conducts management reviews of the QMS twice a year in line with ISO 9001 requirements. In addition, continual quality assurance is performed for each application, and a dedicated Quality Assessment Group reviews random samples of completed applications in detail to verify compliance with the PCT Guidelines. The results are documented and reported to management, thereby ensuring objectivity, transparency, and continual improvement in accordance with paragraphs 21.27–21.30.

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.

The Quality Manual of the PTM defines the practices for identifying risks and opportunities, deciding on actions to address them, and checking the effectiveness of those actions.

These practices are reviewed, evaluated, and confirmed by the management of the PTM during management reviews held twice a year.

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).

(i)
The PTM has adopted practices for identifying and analyzing risks, as well as deciding on actions to address them (see 21.13 (ii)–(v) for details). The strategy is renewed in 3–4 year cycles, during which the operational environment is carefully analyzed for strategic purposes.

The PTM uses various methods to understand the needs and expectations of interested parties, including customers, appeal courts, international organizations, and other patent offices. Special attention is paid to understanding customers' needs through multiple channels, such as:

- customer feedback (online forms),
- customer relationship management (e.g. key account managers),
- customer satisfaction surveys, and
- discussion panels with patent attorneys etc.

Each appeal court decision is reviewed by the Head of the Examination Division, and a summary is presented to the Patent Process Management Group. Where necessary, changes to processes, training programs, or other measures are agreed. A summary of all recent appeal court decisions is also discussed in the management review.

(ii)–(v)

Risks and opportunities are first identified by the owners of the patent process, its sub-processes, and supporting processes (e.g. formalities, legal affairs, ICT maintenance). The identified risks and opportunities are then consolidated and analyzed by the Patent Process Management Group. Each risk is assessed in terms of probability and impact, leading to an overall risk level. Possible actions to address the risks are identified.

The management of the PTM confirms the risk levels and decides on actions for risks that exceed the acceptable level. The acceptable risk level has been predefined by the management of the PTM.

The Patent Process Management Group monitors the implementation of actions, evaluates their effectiveness, and reports the results to the PTM management. In the management review, PTM management considers the reported actions. If the actions or their effects are deemed inadequate, additional measures are decided.

The Quality Manager of the PTM coordinates the overall risk management activities and participates in the PRH Risk Management Working Group. All risks at PRH are managed using comprehensive risk management software (Inclus).

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

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.

(i)

Management continuously monitors performance outcomes, the number of applications, person-years, processing times, and backlogs. Resource management is supported by the following documents and records: the grounds for calculating performance (pieces of work) and productivity; statistics and calculations prepared by the Head of Division responsible for resource follow-up; annual statistics from the performance and productivity system; monthly statistics on the number of applications, 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 PRH planning, such as the operational and financial plan, the annual planning chart, and the strategy year clock. Forecasts are prepared concerning the development of application numbers, changes in activities and work practices, and anticipated staff departures.

Based on the initial data and forecasts, management estimates the human resources needed to achieve processing time and quality objectives, as well as the resources required to clear backlogs. The estimate of person-years per piece of work is used to calculate the resources required by each division. Recruitment is based on these calculations, the assessments of the Heads of Divisions, and financial considerations. All examiners are required to hold a university degree (a doctoral degree is considered an advantage) and to have good proficiency in several languages.

Two examiners were recruited in 2025. The current total number of examiners is 111.

(ii)

The Administration of the PRH is responsible for planning, finances, human resources, international and legal affairs, communications, and data administration, insofar as these matters have not been delegated to other units within the PRH. At the PTM, the Formalities Unit and the PCT Unit are responsible for examining the formal requirements of national and PCT applications, respectively. New employees receive personal training, and complementary training is provided when necessary. Job descriptions define the tasks assigned to each employee of the PRH and specify the required qualifications, including education, work experience, and skills.

A competence management system is used in recruitment, performance assessment, career planning, and the development of learning plans. The career path framework defines various career options within the PRH for experts, including Patent Examiners.

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)–(iv)

The purpose of the PRH IT services is to meet the requirements and expectations specified in the service level agreements concerning the IT systems used by the PTM. The task of the IT services is to ensure uninterrupted processing of applications, efficient searches and examinations, and reliable patent administration. The IT staff, the strategic cooperation partners of the PTM, and active involvement in the European IT development within the EPO ensure that the PRH has the resources required to provide these services. The Information Management of the PRH is in charge of IT services. At office level, the Project Management Office develops enterprise architecture, guides ICT development, and manages the project portfolio.

Processing of PCT and patent applications is fully digitized, and an electronic document service is available for customers. All documents are maintained in electronic form. The PRH uses a production control system for managing PCT and patent applications. The purpose of this system is to allocate workload among examiners efficiently and fairly, thereby minimizing deviations in response times for applicants. The PCT filing system was launched in September 2025.

All examiners have electronic access to more than 100 databases comprising the minimum documentation required under Rule 34 PCT. Databases are accessed through the ANSERA-based Search Tool (ABS) or other tools such as STN. The AI-based search tool IPRally is also in use, and PRH currently utilizes its cloud-based version for searches.

(v)

The PRH has established and maintains documented instructions and process descriptions to ensure that examiners understand and adhere to the quality criteria and work procedures in international search and examination. These internal guidelines cover all stages of the PCT process and are made available to staff through the PRH intranet and the PTM Wiki (Confluence), which serve as the central platforms for controlled documentation and version management. The instructions are reviewed and updated regularly by the process owners to ensure continued alignment with PCT requirements, ISO 9001 standards and internal quality objectives.

The Patent Manual ("Patenttikäsikirja"), published in Finnish and available on the PRH website, provides general information on national patent, PCT application and utility model procedures for external users.

In addition, the PRH intranet and PTM Wiki contain examiner guidelines, IT and security instructions, classification guidance and other materials supporting staff in following work procedures accurately and consistently. Access rights and version control ensure that all staff use the latest approved instructions.

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)

A working group on training issues is responsible for planning and organizing examiner training and for evaluating its effectiveness. New examiners receive training under a qualification program and are introduced to their work under the guidance of personal tutors. Staff members maintain and develop their professional skills by participating in courses on patent matters, IT, languages, and technical specializations.

Training also covers aspects related to the quality of search and examination. The continuous review procedure carried out by Principal Examiners and Heads of Division forms part of the daily quality training. In addition, audit results and corrective actions are reviewed within the processes, so that staff are involved in learning from quality feedback and applying it in practice.

Training activities are systematically recorded in the HR "Osaava" system, which provides an overview of completed training. The national "eOppiva" digital learning environment is also available to all staff for online courses. Furthermore, individual training and development goals are discussed and set annually during development dialogues.

The Lean training program for 2023–2025 was completed in spring 2025 and involved 23 PTM employees. It supported the continual improvement of processes and strengthened staff competences in improvement methodologies.

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.

See previous points in this section (3) and the next section (4).

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)
The processing times of applications in their various phases are continuously monitored by a computerized administrative system. The quality objectives, including timeliness standards, are defined by the PTM Management Group. Heads of Division and Principal Examiners have real-time access to workload and case status and are responsible for ensuring that reports are issued within the required timeframes. The quality of search and examination reports is controlled through review procedures by Principal Examiners and Heads of Divisions, internal audits, and the Quality Assessment Group, so that corrective measures can be taken if quality deviations are detected.

(ii)
The real-time backlog situation is visible in the administrative system. Heads of Division and Principal Examiners monitor the workload continuously and can reallocate resources or adjust priorities when demand fluctuates. The Patent Process Management Group regularly reviews backlog levels and processing time objectives in management reviews and decides on quarterly objectives as well as corrective or improvement actions, such as temporary redistribution of tasks or process changes, to ensure effective backlog management. In addition, discussions are held with the largest applicants to gain an understanding of expected filing volumes, which supports planning and resource allocation.

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)
Quality assurance at the PRH is carried out both before dispatching the products to the applicant and afterwards. The former is performed continuously on a daily basis by Principal Examiners and Heads of Division, while the latter involves sampling of finalized international applications by the Quality Assessment Group. Two examiners cooperate in the handling of each PCT application: the main examiner carries out the search and prepares the written opinion, and the consulting examiner performs an independent review of the work before dispatch to the applicant. In addition, a Principal Examiner verifies the completeness and consistency of the search report and written opinion, and the Head of Division monitors issued work products on a daily basis.

Structured peer review, oversight by Principal Examiners and Heads of Division, and sampling by the Quality Assessment Group ensure that search and examination reports meet the defined quality standards. These reviews focus on compliance with the PCT International Search and Examination Guidelines and on adherence to internal quality criteria and procedures.

Findings from these reviews are recorded and used as input for training, process improvement, and management reviews to promote consistency, continual improvement, and the prevention of recurring issues.

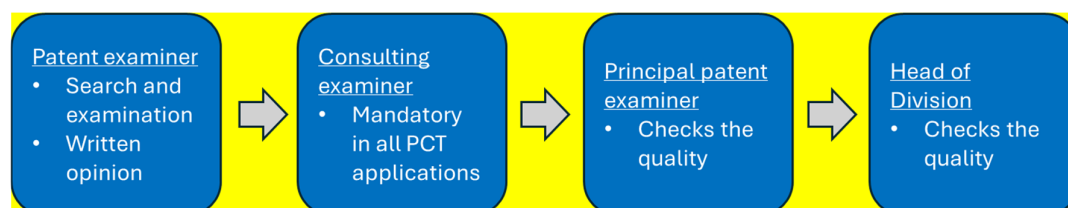


Fig 4. Steps of quality control prior to dispatching international search and examination reports (ISRs/IPRPs).

(ii)

The Quality Assessment Group ensures the good quality of searches, examinations, decisions, reports, and written opinions by examiners. The group carries out several annual rounds, focusing on different types of applications or stages of the process, usually by random sampling but sometimes by other criteria. It measures the quality level of searches and examinations against the defined objectives and determines a quality class for each application process. The results are summarized and reported to the management group of the patent process, and feedback is communicated to staff through process discussions and training.

(iii)

The Quality Assessment Group suggests corrective and preventive actions based on its findings. The management group of the patent process evaluates these actions, implements changes in processes, guidelines, training, or systems, and follows up their effectiveness in subsequent quality assessment rounds. This ensures that deficiencies are corrected, root causes are addressed, and recurring issues are prevented. The management group also prepares material for management reviews and internal and external audits, using information from performance statistics, audit reports, quality assessments, customer feedback, and court decisions.

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.*

(a)...(c)

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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)

Customer complaints concerning the activities of the PTM are forwarded to the relevant unit and official. Both complaints and responses are also forwarded to the Quality Manager. The procedure for handling complaints is described in the instruction "Customer complaints", and the handling of court decisions in the instruction "Court decisions". Feedback is acknowledged, corrective or preventive actions are taken where appropriate, and responses are provided to users.

(ii)

The management group of the patent process gathers, analyses and uses feedback concerning customer satisfaction and court decisions. Information sources include direct communication with customers, written feedback on searches and examinations, feedback from the Contact Committee, customer satisfaction surveys, annual autumn meetings with customers, and appeals to the Market Court and the Supreme Administrative Court. Direct communication covers phone or email contacts related to issued decisions and opinions, as well as informal discussions at training events, fairs, etc.

Customer feedback submitted via the PRH website and internal nonconformities (identified within the Authority) are captured using an intranet-based electronic ticket form and are automatically routed to the Authority's electronic case management system. The system assigns ownership and due dates, supports status tracking and escalation, and provides a complete audit trail. External complaints and feedback are processed in the same workflow, ensuring uniform handling, traceability and reporting across all cases. The Quality Manager has visibility for monitoring and trend analysis.

Customer satisfaction targets and the implementation of surveys are agreed in the result agreement between the Ministry of Economic Affairs and Employment and the PRH. Surveys are carried out by PRH Administration (Planning and Development), and results are analyzed for each unit. Customer relations are also managed through a CRM program: customers are segmented, account managers are appointed for the largest applicants and patent agencies, and a plan is being developed to reach SMEs and start-ups more effectively.

(iii)

A consulting service is available, and clear guidance and information on the search and examination process is provided on the PRH website: www.prh.fi.

Guidance has been designed to support all users, including unrepresented applicants.

(iv) Public availability of quality objectives

The quality goals have been presented to users in the Contact Committee and in the annual autumn meetings. The PRH quality policy and quality indicators are publicly available on the PRH website.

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.

Communication with WIPO is carried out primarily through ePCT and PCT-EDI, and when necessary by email or telephone. Feedback received from WIPO is systematically recorded and evaluated by the PCT Unit of the PRH. If required, amendments are made to the internal guidelines of the PCT Unit (for example detailed checklists), and follow-up is ensured through internal monitoring.

The PRH also communicates with designated and elected Offices as needed, both bilaterally and in international fora. Feedback from these Offices is considered in the same way as feedback from WIPO and, where relevant, results in updates to processes, guidelines, or examiner training to ensure that potential systemic issues are promptly addressed.

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.*

(a)

The quality management system of the PTM is documented in the Quality Manual, the quality policy and quality objectives, as well as statutes, guidelines and other instructions relevant to planning and operations. In addition, procedural guidelines, process descriptions, agendas, minutes of meetings, reports of the Quality Assessment Group, internal and external audit reports, annual audit plans, and results of customer and staff satisfaction surveys form part of the documentation.

(b)

The Quality Manual, as well as all documents and records of the QMS, are maintained in the PTM Wiki (Confluence). Statutes and guidelines are also available in the PRH intranet. All materials are accessible to authorized personnel.

(c)

The Quality Manual is version-controlled and approved by the Quality Manager, and the approval date is recorded. In Confluence, each document includes the author, controller, approver, version number and date. Records such as minutes, audit reports and surveys cannot be altered once approved. Detailed guidelines are in place for document and record control.

Archiving follows the PRH archive formation plan, prepared in line with the National Archives Service guidelines. The plan defines for each document its subject matter, registration, filing and storage, publicity, retention times, and interrelationships with other data. Non-public documents are stored securely, and destruction is handled through locked bins.

In addition to publicly available materials, the internal examiner instructions, process descriptions, and detailed procedural guidelines relevant to international search and examination are maintained on the PRH intranet and the PTM Wiki (Confluence). These internal resources constitute the primary reference for examiners and ensure that the latest approved instructions are consistently applied across all PCT operations.

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.*

See previous points.

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 8.*

See previous points.

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)

The examiner is required to complete an electronic search record form, which includes:

- the databases consulted (patent and non-patent literature, including AI-based search tools);
- 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, CPC 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;
- details of internet searching;
- reference material consulted (e.g. technical books);
- consulted persons; and
- notes concerning clarity, unity, non-patentability or other special issues.

The completed records are stored electronically and are used by the Quality Assessment Group in their assessments as a basis for monitoring and improving the search process.

(c)

Special cases are documented and records are kept denoting, for example:

- limitation of search and its justification;
- lack of clarity of the claims; and
- lack of unity.

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.

The PTM carries out internal audits twice a year in order to determine whether the quality management system meets applicable requirements and **complies with** the plans, standards and requirements set by the organization itself, and whether the system is **effectively** implemented and maintained. Guidelines have been issued for the internal audit procedure, **describing how audits are planned, conducted and reported**, and how corrective actions are controlled.

The results of the internal audits are presented to the management group of the patent process, **which analyses the outcomes and decides** on changes and improvements to processes, guidelines and training. The group may also make proposals to the PTM management group. **The results are communicated within the processes concerned, so that staff are aware of the findings and participate in the implementation of corrective and preventive measures.**

In addition to the internal audits, the quality management system of the PTM **is assessed once** a year by an independent and impartial certification body, which conducts an external audit. **These external assessments provide further assurance of the objectivity and transparency of the review system.**

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 annual reports in accordance with paragraph 21.31(b). 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 PTM complies with the reporting arrangements under paragraph 21.31. An initial full report has been submitted, and annual reports are provided to the MIA with changes from the previous year clearly highlighted.

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